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(54) **SURGICAL ACCESS SYSTEM AND RELATED METHODS**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

208,227 A 9/1878 Dorr
972,983 A 10/1910 Arthur
(Continued)

FOREIGN PATENT DOCUMENTS

DE 299 08 259 7/1999
DE 100 48 790 4/2002
(Continued)

OTHER PUBLICATIONS

Anatomy of the Lumbar Spine in MED TM MicroEndoscopic Discectomy (1997 Ludann Grand Rapids MI), 14 pgs.
(Continued)

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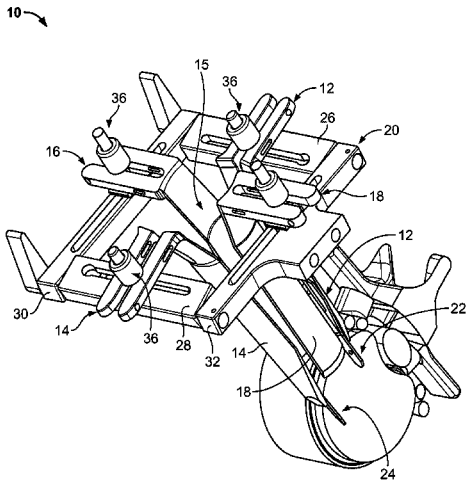
(57) **ABSTRACT**

A system for accessing a surgical target site and related methods, involving an initial distraction system for creating an initial distraction corridor, and an assembly capable of distracting from the initial distraction corridor to a secondary distraction corridor and thereafter sequentially receiving a plurality of retractor blades for retracting from the secondary distraction corridor to thereby create an operative corridor to the surgical target site, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the establishment of an operative corridor to a surgical target site.

19 Claims, 17 Drawing Sheets



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(56) **References Cited**

U.S. PATENT DOCUMENTS

1,003,232	A	10/1910	Cerbo
1,044,348	A	6/1912	Cerbo
1,328,624	A	1/1920	Graham
1,548,184	A	8/1925	Cameron
1,919,120	A	7/1933	O'Connor et al.
2,594,086	A	4/1952	Smith
2,704,064	A	3/1955	Fizzell et al.
2,736,002	A	2/1956	Oriel
2,808,826	A	10/1957	Reiner et al.
3,364,929	A	1/1968	Ide et al.
3,664,329	A	5/1972	Naylor
3,682,162	A	8/1972	Colyer
3,785,368	A	1/1974	McCarthy et al.
3,803,716	A	4/1974	Garnier
3,830,226	A	8/1974	Staub et al.
3,957,036	A	5/1976	Normann
D245,789	S	9/1977	Shea et al.
4,099,519	A	7/1978	Warren
4,164,214	A	8/1979	Stark et al.
4,207,897	A	6/1980	Lloyd et al.
4,224,949	A	9/1980	Scott et al.
4,226,228	A	10/1980	Shin et al.
4,226,288	A	10/1980	Collins, Jr.
4,235,242	A	11/1980	Howson et al.
4,285,347	A	8/1981	Hess
4,291,705	A	9/1981	Severinghaus et al.
4,449,532	A	5/1984	Storz
4,461,300	A	7/1984	Christensen
4,512,351	A	4/1985	Pohndorf
4,515,168	A	5/1985	Chester et al.
4,519,403	A	5/1985	Dickhudt
4,545,374	A	10/1985	Jacobson
4,561,445	A	12/1985	Berke et al.
4,562,832	A	1/1986	Wilder et al.
4,573,448	A	3/1986	Kambin
4,592,369	A	6/1986	Davis et al.
4,595,013	A	6/1986	Jones et al.
4,595,018	A	6/1986	Rantala
4,611,597	A	9/1986	Kraus
4,616,635	A	10/1986	Caspar et al.
4,633,889	A	1/1987	Talalla
4,658,835	A	4/1987	Pohndorf
D295,445	S	4/1988	Freeman
4,744,371	A	5/1988	Harris
4,753,223	A	6/1988	Bremer
4,759,377	A	7/1988	Dykstra
4,784,150	A	11/1988	Voorhies et al.
4,807,642	A	2/1989	Brown
D300,561	S	4/1989	Asa et al.
4,892,105	A	1/1990	Prass
4,913,134	A	4/1990	Luque
4,917,274	A	4/1990	Asa et al.
4,917,704	A	4/1990	Frey et al.
4,926,865	A	5/1990	Oman
4,950,257	A	8/1990	Hibbs et al.
4,962,766	A	10/1990	Herzon
4,964,411	A	10/1990	Johnson et al.
5,007,902	A	4/1991	Witt
5,015,247	A	5/1991	Michelson
5,045,054	A	9/1991	Hood et al.
5,052,373	A	10/1991	Michelson
5,058,602	A	10/1991	Brody
5,081,990	A	1/1992	Deletis
5,092,344	A	3/1992	Lee
5,127,403	A	7/1992	Brownlee
5,161,533	A	11/1992	Prass et al.
5,171,279	A	12/1992	Mathews
5,192,327	A	3/1993	Brantigan
5,195,541	A	3/1993	Obenchain
5,196,015	A	3/1993	Neubardt
5,215,100	A	6/1993	Spitz et al.
RE34,390	E	9/1993	Culver
D340,521	S	10/1993	Heinzelman et al.
5,255,691	A	10/1993	Otten
5,282,468	A	2/1994	Klepinski
5,284,153	A	2/1994	Raymond et al.
5,284,154	A	2/1994	Raymond et al.
5,295,994	A	3/1994	Bonutti
5,299,563	A	4/1994	Seton
5,312,417	A	5/1994	Wilk
5,313,956	A	5/1994	Knutsson et al.
5,313,962	A	5/1994	Obenchain
5,327,902	A	7/1994	Lemmen
5,331,975	A	7/1994	Bonutti
5,333,618	A	8/1994	Lekhtman et al.
5,342,384	A	8/1994	Sugarbaker
5,357,983	A	10/1994	Mathews
5,375,067	A	12/1994	Berchin
5,375,594	A	12/1994	Cueva
5,383,876	A	1/1995	Nardella
5,395,317	A	3/1995	Kambin
5,450,845	A	9/1995	Axelgaard
5,472,426	A	12/1995	Bonati et al.
5,474,057	A	12/1995	Makower et al.
5,474,558	A	12/1995	Neubardt
5,480,440	A	1/1996	Kambin
5,482,038	A	1/1996	Ruff
5,484,437	A	1/1996	Michelson
5,487,739	A	1/1996	Aebischer et al.
5,509,893	A	4/1996	Pracas
5,514,153	A	5/1996	Bonutti
5,540,235	A	7/1996	Wilson
5,549,656	A	8/1996	Reiss
5,560,372	A	10/1996	Cory
5,566,678	A	10/1996	Cadwell
5,569,290	A	10/1996	McAfee
5,571,149	A	11/1996	Liss et al.
5,579,781	A	12/1996	Cooke
5,593,429	A	1/1997	Ruff
5,599,279	A	2/1997	Slotman et al.
5,630,813	A	5/1997	Kieturakis
5,667,508	A	9/1997	Errico et al.
5,671,752	A	9/1997	Sinderby et al.
5,681,265	A	10/1997	Maeda et al.
5,688,223	A	11/1997	Rosendahl
5,707,359	A	1/1998	Bufalini
5,711,307	A	1/1998	Smits
5,728,046	A	3/1998	Mayer et al.
5,741,253	A	4/1998	Michelson
5,741,261	A	4/1998	Moskovitz et al.
5,759,159	A	6/1998	Masreliez
5,762,629	A	6/1998	Kambin
5,772,661	A	6/1998	Michelson
5,775,331	A	7/1998	Raymond et al.
5,776,144	A	7/1998	Leysieffer et al.
5,779,642	A	7/1998	Nightengale

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,785,658 A 7/1998 Benaron
5,792,044 A 8/1998 Foley et al.
5,797,854 A 8/1998 Hedgecock
5,797,909 A 8/1998 Michelson
5,814,073 A 9/1998 Bonutti
5,830,151 A 11/1998 Hadzic et al.
5,851,191 A 12/1998 Gozani
5,853,373 A 12/1998 Griffith et al.
5,860,973 A 1/1999 Michelson
5,862,314 A 1/1999 Jeddeloh
5,872,314 A 2/1999 Clinton
5,885,210 A 3/1999 Cox
5,885,219 A 3/1999 Nightengale
5,888,196 A 3/1999 Bonutti
5,891,147 A 4/1999 Moskovitz et al.
5,902,231 A 5/1999 Foley et al.
5,928,139 A 7/1999 Koros et al.
5,928,158 A 7/1999 Aristides
5,931,777 A 8/1999 Sava
5,935,131 A 8/1999 Bonutti et al.
5,938,688 A 8/1999 Schiff
5,944,658 A * 8/1999 Koros et al. 600/232
5,976,094 A 11/1999 Gozani et al.
6,004,262 A 12/1999 Putz et al.
6,004,312 A 12/1999 Finneran
6,007,487 A 12/1999 Foley et al.
6,010,520 A 1/2000 Pattison
6,024,696 A 2/2000 Hoftman et al.
6,024,697 A 2/2000 Pisarik
6,027,456 A 2/2000 Feler et al.
6,038,469 A 3/2000 Karlsson et al.
6,038,477 A 3/2000 Kayyali
6,050,992 A 4/2000 Nichols
6,074,343 A 6/2000 Nathanson et al.
6,080,105 A 6/2000 Spears
6,083,154 A 7/2000 Liu et al.
6,095,987 A 8/2000 Shmulewitz
6,104,957 A 8/2000 Alo et al.
6,104,960 A 8/2000 Duysens et al.
6,120,503 A 9/2000 Michelson
6,126,660 A 10/2000 Dietz
6,132,386 A 10/2000 Gozani et al.
6,132,387 A 10/2000 Gozani et al.
6,135,965 A 10/2000 Tumer et al.
6,139,493 A 10/2000 Koros et al.
6,142,931 A 11/2000 Kaji
6,146,335 A 11/2000 Gozani
6,152,871 A 11/2000 Foley et al.
6,159,179 A 12/2000 Simonson
6,161,047 A 12/2000 King et al.
6,174,311 B1 1/2001 Branch et al.
6,181,961 B1 1/2001 Prass
6,196,969 B1 3/2001 Bester et al.
6,206,826 B1 3/2001 Mathews et al.
6,217,509 B1 4/2001 Foley et al.
6,224,545 B1 * 5/2001 Cocchia et al. 600/233
6,224,549 B1 5/2001 Drongelen
6,245,082 B1 6/2001 Gellman et al.
6,259,945 B1 7/2001 Epstein et al.
6,264,651 B1 7/2001 Underwood et al.
6,266,558 B1 7/2001 Gozani et al.
6,273,905 B1 8/2001 Streeter
6,292,701 B1 9/2001 Prass et al.
6,306,100 B1 10/2001 Prass
6,308,712 B1 10/2001 Shaw
6,312,392 B1 11/2001 Herzon
6,325,764 B1 12/2001 Griffith et al.
6,334,068 B1 12/2001 Hacker
6,348,058 B1 2/2002 Melkent et al.
6,360,750 B1 3/2002 Gerber et al.
6,371,968 B1 4/2002 Kogasaka et al.
6,395,007 B1 5/2002 Bhatnagar et al.
6,416,465 B2 7/2002 Brau
6,425,859 B1 7/2002 Foley et al.
6,425,887 B1 7/2002 McGuckin et al.
6,425,901 B1 7/2002 Zhu et al.
6,450,952 B1 9/2002 Rioux et al.
6,451,015 B1 9/2002 Rittman, III et al.
6,466,817 B1 10/2002 Kaula et al.
6,468,205 B1 10/2002 Mollenauer et al.
6,468,207 B1 10/2002 Fowler, Jr.
6,500,116 B1 12/2002 Knapp
6,500,128 B2 12/2002 Marino
6,520,907 B1 2/2003 Foley et al.
6,524,320 B2 2/2003 DiPoto
6,535,759 B1 3/2003 Epstein et al.
6,564,078 B1 5/2003 Marino et al.
6,579,244 B2 6/2003 Goodwin
6,599,294 B2 7/2003 Fuss et al.
6,620,157 B1 9/2003 Dabney et al.
6,645,194 B2 11/2003 Briscoe et al.
6,679,833 B2 1/2004 Smith et al.
6,719,692 B2 4/2004 Kleffner et al.
6,760,616 B2 7/2004 Hoey et al.
6,770,074 B2 8/2004 Michelson
6,796,985 B2 9/2004 Bolger et al.
6,810,281 B2 10/2004 Brock et al.
6,819,956 B2 11/2004 DiLorenzo
6,829,508 B2 12/2004 Schulman et al.
6,847,849 B2 1/2005 Mamo et al.
6,849,047 B2 2/2005 Goodwin
6,855,105 B2 2/2005 Jackson, III et al.
6,869,398 B2 3/2005 Obenchain
6,871,099 B1 3/2005 Whitehurst et al.
6,902,569 B2 6/2005 Parmer et al.
6,916,330 B2 7/2005 Simonson
6,926,728 B2 8/2005 Zucherman et al.
6,929,606 B2 8/2005 Ritland
6,945,933 B2 9/2005 Branch
6,951,538 B2 10/2005 Ritland
7,047,082 B1 5/2006 Schrom et al.
7,050,848 B2 5/2006 Hoey et al.
7,079,883 B2 7/2006 Marino et al.
7,089,059 B1 8/2006 Pless
7,177,677 B2 2/2007 Kaula et al.
7,198,598 B2 4/2007 Smith et al.
7,207,949 B2 4/2007 Miles et al.
7,226,451 B2 6/2007 Shluzas et al.
7,261,688 B2 8/2007 Smith et al.
7,470,236 B1 12/2008 Kelleher et al.
7,473,222 B2 1/2009 Dewey et al.
7,481,766 B2 1/2009 Lee et al.
7,522,953 B2 4/2009 Kaula et al.
7,556,601 B2 7/2009 Branch et al.
7,582,058 B1 9/2009 Miles et al.
7,643,884 B2 1/2010 Pond et al.
7,691,057 B2 4/2010 Miles et al.
7,693,562 B2 4/2010 Marino et al.
7,717,959 B2 5/2010 William et al.
7,819,801 B2 10/2010 Miles et al.
7,935,051 B2 5/2011 Miles et al.
8,000,782 B2 8/2011 Gharib et al.
8,005,535 B2 8/2011 Gharib et al.
8,021,430 B2 9/2011 Michelson
8,133,173 B2 3/2012 Miles et al.
8,182,423 B2 5/2012 Miles et al.
8,192,356 B2 6/2012 Miles et al.
8,251,997 B2 8/2012 Michelson
8,303,458 B2 11/2012 Fukano et al.
8,343,046 B2 1/2013 Miles et al.
8,343,224 B2 1/2013 Lynn et al.
8,388,527 B2 3/2013 Miles
8,740,783 B2 6/2014 Gharib et al.
2001/0039949 A1 11/2001 Loubser
2001/0056280 A1 12/2001 Underwood et al.
2002/0007129 A1 1/2002 Marino
2002/0010392 A1 1/2002 Desai
2002/0072686 A1 6/2002 Hoey et al.
2002/0077632 A1 6/2002 Tsou
2002/0123744 A1 9/2002 Reynard
2002/0123780 A1 9/2002 Grill et al.
2002/0161415 A1 10/2002 Cohen et al.
2002/0193843 A1 12/2002 Hill et al.
2003/0032966 A1 2/2003 Foley et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2003/0070682	A1	4/2003	Wilson et al.
2003/0083688	A1	5/2003	Simonson
2003/0105503	A1	6/2003	Marino
2003/0139648	A1	7/2003	Foley et al.
2003/0149341	A1	8/2003	Clifton
2003/0225405	A1	12/2003	Weiner
2003/0236544	A1	12/2003	Lunsford et al.
2004/0199084	A1	10/2004	Kelleher et al.
2004/0225228	A1	11/2004	Ferree
2005/0004593	A1	1/2005	Simonson
2005/0004623	A1	1/2005	Miles et al.
2005/0033380	A1	2/2005	Tanner et al.
2005/0075578	A1	4/2005	Gharib et al.
2005/0080320	A1	4/2005	Lee et al.
2005/0149035	A1	7/2005	Pimenta et al.
2005/0182454	A1	8/2005	Gharib et al.
2005/0192575	A1	9/2005	Pacheco
2006/0025703	A1	2/2006	Miles et al.
2006/0052828	A1	3/2006	Kim et al.
2006/0069315	A1	3/2006	Miles et al.
2006/0224078	A1	10/2006	Hoey et al.
2007/0016097	A1	1/2007	Farquhar et al.
2007/0198062	A1	8/2007	Miles et al.
2007/0293782	A1	12/2007	Marino
2008/0058606	A1	3/2008	Miles et al.
2008/0058838	A1	3/2008	Steinberg
2008/0064976	A1	3/2008	Kelleher et al.
2008/0064977	A1	3/2008	Kelleher et al.
2008/0065144	A1	3/2008	Marino et al.
2008/0065178	A1	3/2008	Kelleher et al.
2008/0071191	A1	3/2008	Kelleher et al.
2008/0097164	A1	4/2008	Miles et al.
2008/0300465	A1	12/2008	Feigenwinter et al.
2009/0124860	A1	5/2009	Miles et al.
2009/0138050	A1	5/2009	Ferree
2009/0192403	A1	7/2009	Gharib et al.
2009/0204016	A1	8/2009	Gharib et al.
2010/0069783	A1	3/2010	Miles et al.
2010/0130827	A1	5/2010	Pimenta et al.
2010/0152603	A1	6/2010	Miles et al.
2010/0160738	A1	6/2010	Miles et al.
2010/0174146	A1	7/2010	Miles
2010/0174148	A1	7/2010	Miles et al.
2011/0313530	A1	12/2011	Gharib et al.
2012/0238822	A1	9/2012	Miles
2012/0238893	A1	9/2012	Farquhar et al.

FOREIGN PATENT DOCUMENTS

EP	0 334 116	9/1989
EP	0 567 424	10/1993
EP	0 972 538	1/2000
EP	1 002 500	5/2000
FR	2 795 624	1/2001
JP	793186	5/1990
JP	10-14928	3/1996
KR	3019990007098	11/1999
WO	94/28824	12/1994
WO	97/00702	1/1997
WO	98/23324	6/1998
WO	99/52446	10/1999
WO	00/27291	5/2000
WO	00/38574	7/2000
WO	00/44288	8/2000
WO	00/66217	11/2000
WO	00/67645	11/2000
WO	01/08563	2/2001
WO	01/37728	5/2001
WO	01/60263	8/2001
WO	02/054960	7/2002
WO	02/058780	8/2002
WO	02/071953	9/2002
WO	02/087678	11/2002
WO	03/005887	1/2003
WO	03/026482	4/2003
WO	03/037170	5/2003
WO	2005/013805	2/2005
WO	2005/030318	4/2005
WO	2006/042241	4/2006
WO	2006/066217	6/2006

OTHER PUBLICATIONS

Dirksmeier et al., "Microendoscopic and Open Laminotomy and Discectomy in Lumbar Disc Disease" *Seminars in Spine Surgery*, 1999, 11(2): 138-146.

METRx Delivered Order Form, 1999, 13 pages.

Medtronic Sofamor Danek "METRx™ MicroDiscectomy System," *Medtronic Sofamor Danek USA*, 2000, 21 pgs.

Medtronic Sofamor Danek "METRx System Surgical Technique," 2004, 22 pages.

"MetRx System MicroEndoscopic Discectomy: An Evolution in Minimally Invasive Spine Surgery," *Sofamor Danek*, 1999, 6 pages.

Smith and Foley "MetRx System MicroEndoscopic Discectomy: Surgical Technique" *Medtronic Sofamor Danek*, 2000, 24 pages.

"Sofamor Danek MED Microendoscopic Discectomy System Brochure" including Rapp "New endoscopic lumbar technique improves access preserves tissue" Reprinted with permission from: *Orthopedics Today*, 1998, 18(1): 2 pages.

Japanese Patent Office JP Patent Application No. 2006-528306 Office Action with English Translation, Jun. 10, 2009, 4 pages.

Plaintiffs' Preliminary Invalidity Contentions re U.S. Pat. Nos. 7207949; 7470236 and 7582058, Sep. 18, 2009, 19 pages.

Plaintiffs' Preliminary Invalidity Contentions-Appendices, Sep. 18, 2009, 191 pages.

Plaintiffs' Supplemental Preliminary Invalidity Contentions re U.S. Pat. Nos. 7207949, 7470236, and 7582058, Sep. 29, 2009, 21 pages.

Plaintiffs' Supplemental Preliminary Invalidity Contentions-Appendices, Sep. 29, 2009, 294 pages.

Axon 501(k) Notification: Epoch 2000 Neurological Workstation, Dec. 3, 1997, 464 pages.

Foley and Smith, "Microendoscopic Discectomy," *Techniques in Neurosurgery*, 1997, 3(4):301-307.

Medtronic Sofamor Danek "UNION™ / Union-L™ Anterior & Lateral Impacted Fusion Devices: Clear choice of stabilization," *Medtronic Sofamor Danek*, 2000, 4 pages.

NuVasive Vector™ Cannulae, 2000, 1 page.

NuVasive Triad™ Tri-Columnar Spinal EndoArthrodesis™ via Minimally Invasive Guidance, 2000, 1 page (prior to Sep. 25, 2003).

NuVasive Triad™ Cortical Bone Allograft, 2000, 1 page (prior to Sep. 25, 2003).

NuVasive Vertebral Body Access System, 2000, 1 page.

Marina, "New Technology for Guided Navigation with Real Time Nerve Surveillance for Minimally Invasive Spine Discectomy & Arthrodesis," *Spineline*, 2000, p. 39.

NuVasive "INS-1 Screw Test," 2001, 10 pages.

NuVasive letter re 510k Neuro Vision JJB System, Oct. 16, 2001, 5 pages.

NuVasive letter re 510k Guided Arthroscopy System, Oct. 5, 1999, 6 pages.

NuVasive letter re 510k INS-1 Intraoperative Nerve Surveillance System, Nov. 13, 2000, 7 pages.

"NuVasiveTM Receives Clearance to Market Two Key Elem Minimally Invasive Spine Surgery System," Nov. 27, 2001, 20 pages.

Schick et al., "Microendoscopic lumbar discectomy versus open surgery: an intraoperative EMG study," *Eur Spine J*, 2002, 11: 20-26.

NuVasive letter re: 510(k) for Neurovision JJB System (Summary), Sep. 25, 2001, 28 pages.

NuVasive letter re: Special 510(k) Premarket Notification: Neurovision JJB System (Device Description), Jul. 3, 2003, 18 pages.

NuVasive letter re: Special 510(k) Premarket Notification: Neurovision JJB System (Device Description), Mar. 1, 2004, 16 pages.

NuVasive letter re: Special 510(k) Premarket Notification: Neurovision JJB System (Device Description), May 26, 2005, 17 pages.

NuVasive letter re: 510(k) Premarket Notification: Neurovision JJB System (Device Description), Jun. 24, 2005, 16 pages.

(56) **References Cited**

OTHER PUBLICATIONS

NuVasive letter re: Special 510(k) Premarket Notification: Neurovision JJB System (Device Description), Sep. 14, 2006, 17 pages.
NuVasive 510(k) Premarket Notification: Neurovision JJB System (Device Description), Aug. 20, 2007, 8 pages.
NuVasive letter re: 510(k) Premarket Notification: Guided Spinal Arthroscopy System (Device Description), Feb. 1, 1999, 40 pages.
NuVasive 510(k) Premarket Notification: Spinal System (Summary), Apr. 12, 2004, 10 pages.
NuVasive 510(k) Summary NIM Monitor, Sep. 4, 1998, 4 pages.
NuVasive correspondence re 510(k) Premarket Notification INS-1 Intraoperative Nerve Surveillance System: Section IV Device Description, pp. 12-51 (prior to Sep. 25, 2003).
Isley et al., "Recent Advances in Intraoperative Neuromonitoring of Spinal Cord Function: Pedicle Screw Stimulation Techniques," *American Journal of Electroneurodiagnostic Technology*, Jun. 1997, 37(2): 93-126.
Mathews et al., "Laparoscopic Discectomy with Anterior Lumbar Interbody Fusion," *SPINE*, 1995, 20(16): 1797-1802.
Rose et al., "Persistently Electrified Pedicle Stimulation Instruments in Spinal Instrumentation: Techniques and Protocol Development," *SPINE*, 1997, 22(3): 334-343.
"Electromyography System," International Search report from International Application No. PCT/US00/32329, Apr. 27, 2001, 9 pages.
"Nerve Proximity and Status Detection System and Method," International Search Report from International Application No. PCT/US01/18606, Oct. 18, 2001, 6 pages.
"Relative Nerve Movement and Status Detection System and Method," International Search Report from International Application No. PCT/US01/18579, Jan. 15, 2002, 6 pages.
"System and Method for Determining Nerve Proximity Direction and Pathology During Surgery," International Search Report from International Application No. PCT/US02/22247, Mar. 27, 2003, 4 pages.
"System and Methods for Determining Nerve Direction to a Surgical Instrument," International Search Report from International Application No. PCT/US03/02056, Aug. 12, 2003, 5 pages.
"Systems and Methods for Performing Percutaneous Pedicle Integrity Assessments," International Search Report from International Application No. PCT/US02/35047, Aug. 11, 2003, 5 pages.
"Systems and Methods for Performing Surgery Procedures and Assessments," International Search Report from International Application No. PCT/US02/30617, Jun. 5, 2003, 4 pages.
Lenke et al., "Triggered Electromyographic Threshold for Accuracy of Pedicle Screw Placement," *Spine*, 1995, 20(4): 1585-1591.
"Brackmann II EMG System," *Medical Electronics*, 1999, 4 pages.
"Neurovision SE Nerve Locator/Monitor", RLN Systems Inc. Operators Manual, 1999, 22 pages.
"The Brackmann II EMG Monitoring System," Medical Electronics Co. Operator's Manual Version 1.1, 1995, 50 pages.
"The Nicolet Viking IV," Nicolet Biomedical Products, 1999, 6 pages.
Anderson et al., "Pedicle screws with high electrical resistance: a potential source of error with stimulus-evoked EMG," *Spine*, Department of Orthopaedic Surgery University of Virginia, Jul. 15, 2002, 27(14): 1577-1581.
Bose et al., "Neurophysiologic Monitoring of Spinal Nerve Root Function During Instrumented Posterior Lumber Spine Surgery," *Spine*, 2002, 27(13):1444-1450.
Calancie et al., "Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation" *Spine*, 1994, 19(24): 2780-2786.
Clements et al., "Evoked and Spontaneous Electromyography to Evaluate Lumbosacral Pedicle Screw Placement," *Spine*, 1996, 21(5): 600-604.
Danesh-Clough et al. ,"The Use of Evoked EMG in Detecting Misplaced Thoracolumbar Pedicle Screws," *Spine*, Orthopaedic Department Dunedin Hospital, Jun. 15, 2001, 26(12): 1313-1316.
Darden et al., "A Comparison of Impedance and Electromyogram Measurements in Detecting the Presence of Pedicle Wall Breakthrough," *Spine*, Charlotte Spine Center, North Carolina, Jan. 15, 1998, 23(2): 256-262.
Ebraheim et al., "Anatomic Relations Between the Lumbar Pedicle and the Adjacent Neural Structures," *Spine*, Department of Orthopaedic Surgery Medical College of Ohio, Oct. 15, 1997, 22(20): 2338-2341.
Ford et al. "Electrical Characteristics of Peripheral Nerve Stimulators Implications for Nerve Localization," *Regional Anesthesia*, 1984, 9: 73-77.
Glassman et al., "A Prospective Analysis of Intraoperative Electromyographic Monitoring of Pedicle Screw Placement With Computed Tomographic Scan Confirmation," *Spine*, 1995, 20(12): 1375-1379.
Greenblatt et al., "Needle Nerve Stimulator-Locator: Nerve Blocks with a New Instrument for Locating Nerves," *Anesthesia& Analgesia*, 1962, 41(5): 599-602.
Haig, "Point of view," *Spine*, 2002, 27(24): 2819.
Haig et al., "The Relation Among Spinal Geometry on MRI, Paraspinal Electromyographic Abnormalities, and Age in Persons Referred for Electrodiagnostic Testing of Low Back Symptoms,"0 *Spine*, Department of Physical Medicine and Rehabilitation University of Michigan, Sep. 1, 2002, 27(17): 1918-1925.
Holland et al., "Higher Electrical Stimulus Intensities are Required to Activate Chronically Compressed Nerve Roots: Implications for Intraoperative Electromyographic Pedicle Screw Testing," *Spine*, Department of Neurology, Johns Hopkins University School of Medicine, Jan. 15, 1998, 23(2): 224-227.
Holland, "Intraoperative Electromyography During Thoracolumbar Spinal Surgery," *Spine*, 1998, 23(17): 1915-1922..
Journee et al., "System for Intra-Operative Monitoring of the Cortical Integrity of the Pedicle During Pedicle Screw Placement in Low-Back Surgery: Design and Clinical Results," *Sensory and Neuromuscular Diagnostic Instrumentation and Data Analysis I, 18th Annual International Conference on Engineering in Medicine and Biology Society*, Amsterdam, 1996, pp. 144-145.
Maguire et al., "Evaluation of Intrapedicular Screw Position Using Intraoperative Evoked Electromyography," *Spine*, 1995, 20(9): 1068-1074.
Martin et al. "Initiation of Erection and Semen Release by Rectal Probe Electrostimulation (RPE)," *The Journal of Urology*, The Williams& Wilkins Co., 1983, 129: 637-642.
Minahan et al., "The Effect of Neuromuscular Blockade on Pedicle Screw Stimulation Thresholds" *Spine*, Department of Neurology, Johns Hopkins University School of Medicine, Oct. 1, 2000, 25(19): 2526-2530.
Pither et al., "The Use of Peripheral Nerve Stimulators for Regional Anesthesia: Review of Experimental Characteristics Technique and Clinical Applications," *Regional Anesthesia*, 1985, 10:49-58.
Raj et al., "Infraclavicular Brachial Plexus Block—A New Approach" *Anesthesia and Analgesia*, 1973, (52)6: 897-904.
Raj et al., "The Use of Peripheral Nerve Stimulators for Regional Anesthesia," *Clinical Issues in Regional Anesthesia*, 1985, 1(4):1-6.
Raj et al., "Use of the Nerve Stimulator for Peripheral Blocks," *Regional Anesthesia*, Apr.-Jun. 1980, pp. 14-21.
Raymond et al., "The Nerve Seeker: A System for Automated Nerve Localization," *Regional Anesthesia*, 1992, 17(3): 151-162.
Shafik, "Cavernous Nerve Simulation through an Extrapelvic Subpubic Approach: Role in Penile Erection," *Eur. Uro.* 1994, 26: 98-102.
Toleikis et al., "The Usefulness of Electrical Stimulation for Assessing Pedicle Screw Replacements," *Journal of Spinal Disorder*, 2000, 13(4): 283-289.
Medtronic Sofamor Danek "UNION™ / UNION-L™ Anterior & Lateral Impacted Fusion Devices: Surgical Technique" *Medtronic Sofamor Danek*, 2001, 20 pages.
Defendant's Disclosure of Asserted Claims and Preliminary Infringement Contentions Regarding USP 7207949; 7470236 and 7582058, Aug. 31, 2009, 21 pages.
Bergey et al., "Endoscopic Lateral Transpsoas Approach to the Lumbar Spine," *Spine*, 2004, 29(15): 1681-1688.

(56) **References Cited**

OTHER PUBLICATIONS

Dezawa et al., "Retroperitoneal Laparoscopic Lateral Approach to the Lumbar Spine: A New Approach, Technique, and Clinical Trial," *Journal of Spinal Disorders*, 2000, 13(2): 138-143.
Gardocki, "Tubular diskectomy minimizes collateral damage: A logical progression moves spine surgery forward," *AAOS Now*, 2009, 5 pages.
Hovorka et al., "Five years' experience of retroperitoneal lumbar and thoracolumbar surgery," *Eur Spine J.*, 2000, 9)1): S30-S34.
Kossmann et al., "The use of a retractor system (SynFrame) for open, minimal invasive reconstruction of the anterior column of the thoracic and lumbar spine," *Eur Spine J.*, 2001, 10:396-402.
Mayer, "A New Microsurgical Technique for Minimally Invasive Anterior Lumbar Interbody Fusion," *Spine*, 1997, 22(6): 691-699.
Mayer, "The ALIF Concept," *Eur Spine J.*, 2000, 9(1): S35-S43.
Mayer and Wiechert, "Microsurgical Anterior Approaches to the Lumbar Spine for Interbody Fusion and Total Disc Replacement," *Neurosurgery*, 2002, 51(2): 159-165.
McAfee et al., "Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine: Emphasis on the Lateral BAK," *Spine*, 1998, 23(13): 1476-1484.
Rao, et al. "Dynamic retraction of the psoas muscle to expose the lumbar spine using the retroperitoneal approach," *J. Neurosurg Spine*, 2006, 5: 468-470.
Wolfla et al., "Retroperitoneal lateral lumbar interbody fusion with titanium threaded fusion cages," *J. Neurosurg* (*Spine 1*), 2002, 96: 50-55.
Larson and Maiman, "Surgery of the Lumbar Spine," Thieme Medical Publishers, Inc., 1999, pp. 305-319.
Medtronic XOMED Surgical Products, Inc., NIM-Response Nerve Integrity Monitor Intraoperative EMG Monitor User's Guide, Revision B, 2000, 47 pages.
"NuVasive's spine surgery system cleared in the US," Pharm & Medical Industry Week, Dec. 10, 2001, 1 page.
Pimenta, "Initial Clinical Results of Direct Lateral, Minimally Invasive Access to the Lumbar Spine for Disc Nucleus Replacement Using a Novel Neurophysiological Monitoring System." *The 9th IMAST*, May 2002, 1 page.
Pimenta et al., "The Lateral Endoscopic Transpsoas Retroperitoneal Approach (Letra) for Implants in the Lumbar Spine," *World Spine II-Second Interdisciplinary Congress on Spine Care*, Aug. 2003, 2 pages.
Crock, H.V. MD., "Anterior Lumbar Interbody Fusion," Clinical Orthopaedics and Related Research, Number One Hundred Sixty Five, 1982, pp. 157-163, 13 pages.
Mayer and Brock, "Percutaneous endoscopic discectomy: surgical technique and preliminary results compared to microsurgical discectomy," *J. Neurosurg*, 1993, 78: 216-225.
Schaffer and Kambin, "Percutaneous Posterolateral Lumbar Discectomy and Decompression with a 6.9-Millimeter Cannula," *The Journal of Bone and Joint Surgery*, 1991, 73A(6): 822-831.
Friedman, "Percutaneous discectomy: An alternative to chemonucleolysis," *Neurosurgery*, 1983, 13(5): 542-547.
Request for Inter PartesReexamination in re U.S. Pat. No. 7,905,840, dated Feb. 8, 2012, 204 pages.
Brau, "Chapter 22: Anterior Retroperitoneal Muscle-Sparing approach to L2-S1 of the Lumbar Spine," *Surgical Approaches to the Spine*. Robert G. Watkins, MD. (ed) 2003. pp. 165-181.
Kossmann et al., "Minimally Invasive Vertebral Replacement with Cages in Thoracic and Lumbar Spine," *European Journal of Trauma*, 2001, 27: 292-300.
Mayer H. M. (ed.) *Minimally Invasive Spine Surgery: A Surgical Manual*. 2000. 51 pages.
Pimenta et al., "Implante de protese de nucleo pulposo: analise inicial," *Journal Brasileiro de Neurocirurgia*, 2001, 12(2): 93-96.
Traynelis, "Spinal Arthroplasty," *Neurological Focus*, 2002, 13(2): 12 pages.
Zdeblick, Thomas A. (ed.). Anterior Approaches to the Spine. 1999. 43 pages.
Amended Complaint for *NuVasive, Inc.* v. *Globus Medical, Inc.*, Case No. 1:10-cv-0849 (D. Del., Oct. 5, 2010), 28 pages.
Request for Inter PartesReexamination in re U.S. Pat. No. 7,819,801, dated Feb. 8, 2012, 89 pages.
Kossman et al., "The use of a retractor system (SynFrame) for open, minimal invasive reconstruction of the anterior column of the thoracic and lumbar spine," *Eur Spine J*, 2001, 10: 396-402.
de Peretti et al., "New possibilities in L2-L5 lumbar arthrodesis using a lateral retroperitoneal approach assisted by laparoscopy: preliminary results," *Eur Spine J*, 1996, 5: 210-216.
Litwin et al., "Hand-assisted laparoscopic surgery (HALS) with the handport system," *Annals of Surgery*, 2000, 231(5): 715-723.
Acland's Video Atlas of Human Anatomy, Section 3.1.7: Paravertebral Muscles. Available online: http://aclandanatomy.com/abstract/4010463. Accessed Jul. 11, 2012.
MedlinePlus, a Service of the U.S. National Library of Medicine and National Institutes of Health. Available online: http://www.nlm.nih.gov/medlineplus/. Accessed Jul. 11, 2012.
Baulot et al., Adjuvant Anterior Spinal Fusion via Thoracoscopy, *Lyon Chirurgical*, 1994, 90(5): 347-351 inluding English Translation and Certificate of Translation.
Leu et al., "Percutaneous Fusion of the Lumbar Spine," *Spine*, 1992, 6(3): 593-604.
Rosenthal et al., "Removal of a Protruded Thoracic Disc Using Microsurgical Endoscopy," *Spine*, 1994, 19(9): 1087-1091.
Counterclaim Defendants' Corrected Amended Invalidity Contentions re U.S. Pat. Nos. 8,000,782; 8,005,535; 8,016,767; 8,192,356; 8,187,334; 8,361,156, D652,922; D666,294 re Case No. 3:12-cv-02738-CAB(MDD), dated Aug. 19, 2013, 30 pages.
Petition for Inter Partes Review IPR2014-00034, filed Oct. 8, 2013, 65 pages.
Petition for Inter Partes Review IPR2014-00035, filed Oct. 8, 2013, 65 pages.
Declaration of Lee Grant, from IPR2014-00034, Oct. 7, 2013, 36 pages.
Declaration of David Hacker from IPR2014-00034, Oct. 4, 2013, 64 pages.
NuVasive, Inc's Opening Claim Construction Brief Regarding U.S. Pat. Nos. 8,000,782; 8,005,535; 8,016,767; 8,192,356; 8,187,334; 8,361,156; D652,922; and 5,676,146 C2, filed Sep. 3, 2013, in *Warsaw Orthopedic, Inc.* v. *NuVasive, Inc.*, No. 3:12-cv-02738-CAB-MDD (S.D. Cal.)., 34 pages.
Petition for Inter Partes Review IPR2014-00073, filed Oct. 18, 2013, 65 pages.
Petition for Inter Partes Review IPR2014-00074, filed Oct. 18, 2013, 65 pages.
Petition for Inter Partes Review IPR2014-00075, filed Oct. 21, 2013, 66 pages.
Petition for Inter Partes Review IPR2014-00076, filed Oct. 21, 2013, 65 pages.
Petition for Inter Partes Review IPR2014-00081, filed Oct. 22, 2013, 64 pages.
Petition for Inter Partes Review IPR2014-00087, filed Oct. 22, 2013, 64 pages.
Declaration of Lee Grant, from IPR2014-00073, Oct. 9, 2013, 36 pages.
Declaration of David Hacker, from IPR2014-00073, Oct. 10, 2013, 64 pages.
U.S. Appl. No. 60/392,214, filed Jun. 26, 2002, 97 pages.
Amendment in reply to Feb. 15, 2012 Office Action in U.S. Appl. No. 12/635,418, dated Mar. 16, 2012, 24 pages.
Decision on Appeal in Inter Partes Reexamination Control No. 95/001,247, dated Mar. 18, 2013, 49 pages.
Declaration of Lee Grant, from IPR2014-00074, Oct. 9, 2013, 36 pages.
Declaration of David Hacker, from IPR2014-00074, Oct. 10, 2013, 64 pages.
Declaration of David Hacker, from IPR2014-00075, Oct. 10, 2013, 64 pages.
Amendment in reply to Action of Feb. 7, 2011 and Notice of May 12, 2011, in U.S. Appl. No. 11/789,284, dated May 17, 2011, 16 pages.
Notice of Allowance in U.S. Appl. No. 11/789,284, dated Jul. 18, 2011, 8 pages.

(56) **References Cited**

OTHER PUBLICATIONS

Office action from U.S. Appl. No. 11/789,284, dated Feb. 7, 2011, 10 pages.
Merriam-Webster's Collegiate Dictionary, p. 65 (10th ed. 1998).
Declaration of Lee Grant, from IPR2014-00076, Oct. 9, 2013, 36 pages.
Moed et al., "Evaluation of Intraoperative Nerve-Monitoring During Insertion of an Iliosacral Implant in an Animal Model, *Journal of Bone and Joint Surgery*," 1999, 81-A(11): 9.
Declaration of Lee Grant, from IPR2014-0081, Oct. 9, 2013, 36 pages.
Declaration of David Hacker from IPR2014-00081, Oct. 10, 2013, 64 pages.
U.S. Appl. No. 60/325,424, filed Sep. 25, 2001, 346 pages.
Declaration of Lee Grant, from IPR2014-0087, Oct. 9, 2013, 36 pages.
Declaration of David Hacker from IPR2014-00087, Oct. 10, 2013, 64 pages.
Declaration of Daniel Schwartz, Ph.D. from IPR2014-00034, Oct. 7, 2013, 1056 pages.
Declaration of Daniel Schwartz, Ph.D. from IPR2014-00035, Oct. 7, 2013, 661 pages.
510(K) No. K002677, approved by the FDA on Nov. 13, 2000, 634 pages.
510(K) No. K013215, approved by the FDA on Oct. 16, 2001, 376 pages.
Declaration of Robert G. Watkins, from IPR2014-00073, Oct. 18, 2013, 1101 pages.
Declaration of Daniel Schwartz, from IPR2014-00073, Oct. 12, 2013, 1226 pages.
Declaration of Robert G. Watkins, from IPR2014-00074, Oct. 18, 2013, 548 pages.
Declaration of Daniel Schwartz, from IPR2014-00074, Oct. 12, 2013, 565 pages.
Declaration of Robert G. Watkins, from IPR2014-00075, Oct. 18, 2013, 674 pages.
Declaration of Daniel Schwartz, from IPR2014-00075, Oct. 12, 2013, 1107 pages.
Declaration of Robert G. Watkins, from IPR2014-00076, Oct. 18, 2013, 543 pages.
Declaration of Daniel Schwartz, from IPR2014-00076, Oct. 12, 2013, 1247 pages.
Declaration of David Hacker, from IPR2014-00076, Oct. 10, 2013, 64 pages.
Declaration of Daniel Schwartz, from IPR2014-0081, Oct. 21, 2013, 585 pages.
Declaration of Daniel Schwartz from IPR2014-0087, Oct. 21, 2013, 585 pages.
Patent Owner NuVasive Inc's Preliminary Response from IPR2014-00034, dated Jan. 15, 2014, 66 pages.
Patent Trial and Appeal Board Decision from IPR 2014-00034, dated Apr. 8, 2014, 35 pages.
Patent Owner NuVasive Inc's Preliminary Response from IPR2014-00035, dated Jan. 15, 2014, 42 pages.
Patent Trial and Appeal Board Decision from IPR 2014-00035, dated Apr. 8, 2014, 12 pages.
Patent Owner NuVasive Inc's Preliminary Response from IPR2014-00073, dated Jan. 31, 2014, 64 pages.
Patent Trial and Appeal Board Decision from IPR 2014-00073, dated Apr. 8, 2014, 34 pages.
Patent Owner NuVasive Inc's Preliminary Response from IPR2014-00074, dated Jan. 31, 2014, 68 pages.
Patent Trial and Appeal Board Decision from IPR 2014-00074, dated Apr. 8, 2014, 28 pages.
Patent Owner NuVasive Inc's Preliminary Response from IPR2014-00075, dated Jan. 31, 2014, 54 pages.
Patent Trial and Appeal Board Decision from IPR 2014-00075, dated Apr. 8, 2014, 23 pages.
Patent Owner NuVasive Inc's Preliminary Response from IPR2014-00076, dated Jan. 31, 2014, 58 pages.
Patent Trial and Appeal Board Decision from IPR 2014-00076, dated Apr. 8, 2014, 11 pages.
Patent Owner NuVasive Inc's Preliminary Response from IPR2014-00081, dated Jan. 31, 2014, 47 pages.
Patent Trial and Appeal Board Decision from IPR 2014-00081, dated Apr. 8, 2014, 31 pages.
Patent Owner NuVasive Inc's Preliminary Response from IPR2014-00087, dated Jan. 31, 2014, 51 pages.
Patent Trial and Appeal Board Decision from IPR 2014-00087, dated Apr. 8, 2014, 31 pages.
Final Written Decision from IPR 2014-00034, dated Apr. 3, 2015, 48 pages.
Final Written Decision from IPR 2014-00073, dated Apr. 3, 2015, 36 pages.
Final Written Decision from IPR 2014-00074, dated Apr. 3, 2015, 31 pages.
Final Written Decision from IPR 2014-00075, dated Apr. 3, 2015, 39 pages.
Final Written Decision from IPR 2014-00081, dated Apr. 3, 2015, 44 pages.
Final Written Decision from IPR 2014-00087, dated Apr. 3, 2015, 36 pages.

* cited by examiner

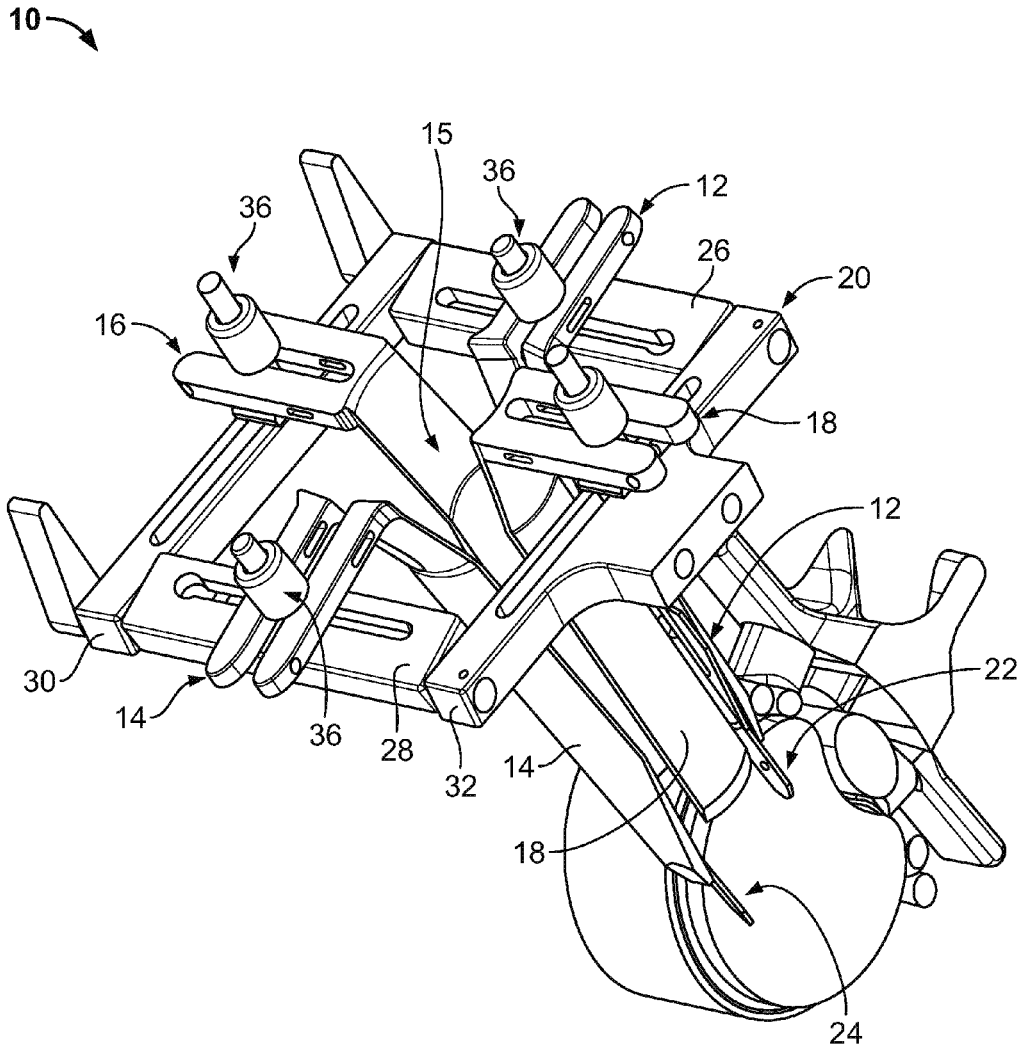

FIG. 1

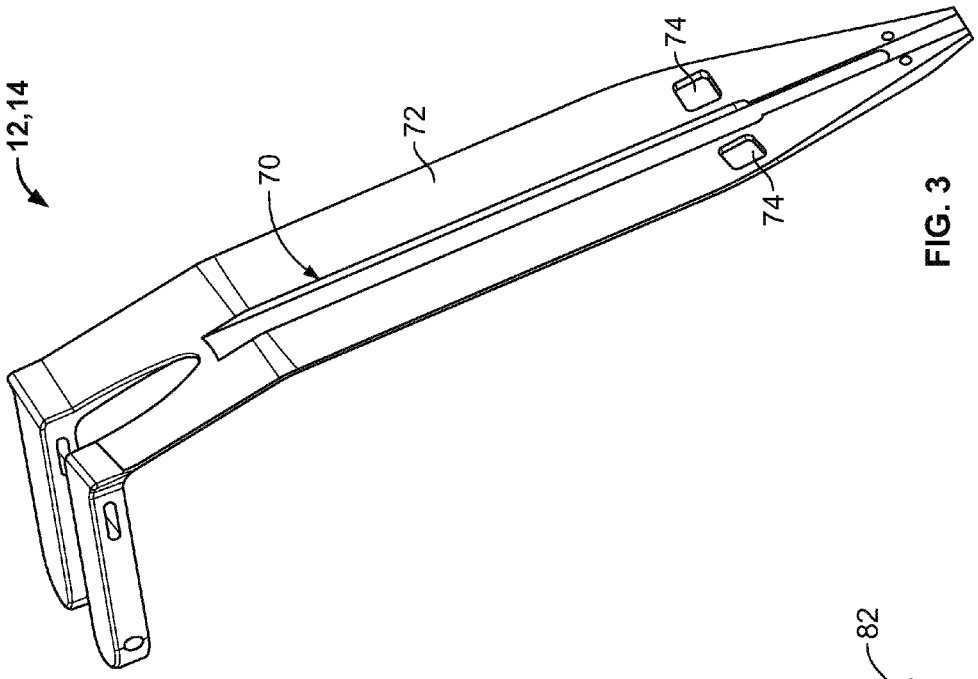

FIG. 3

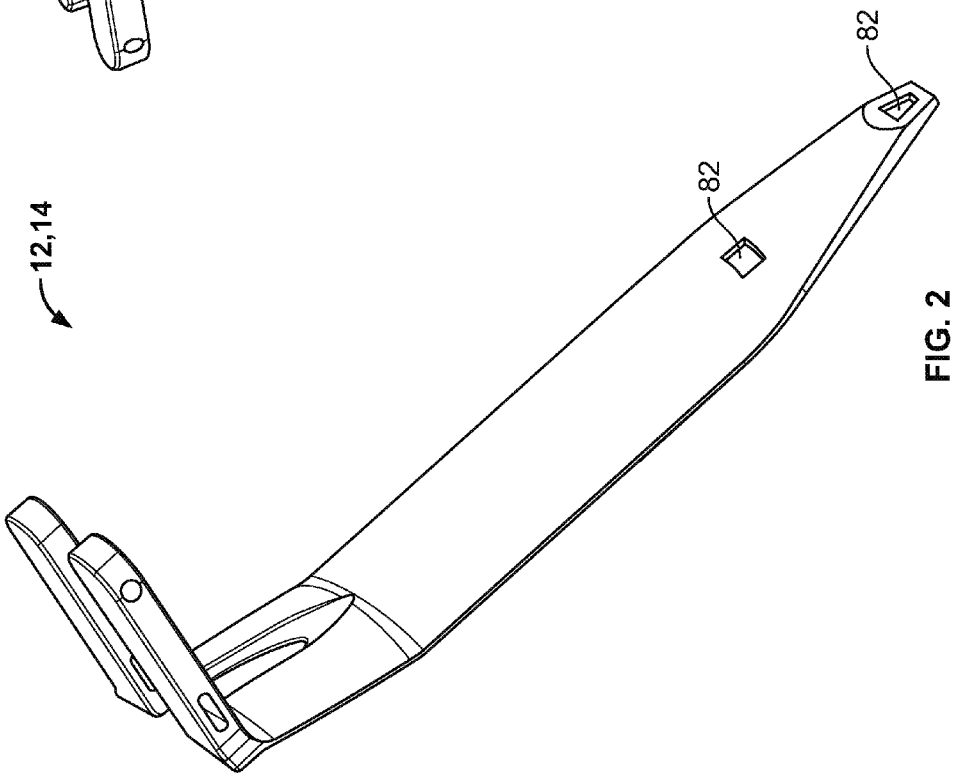

FIG. 2

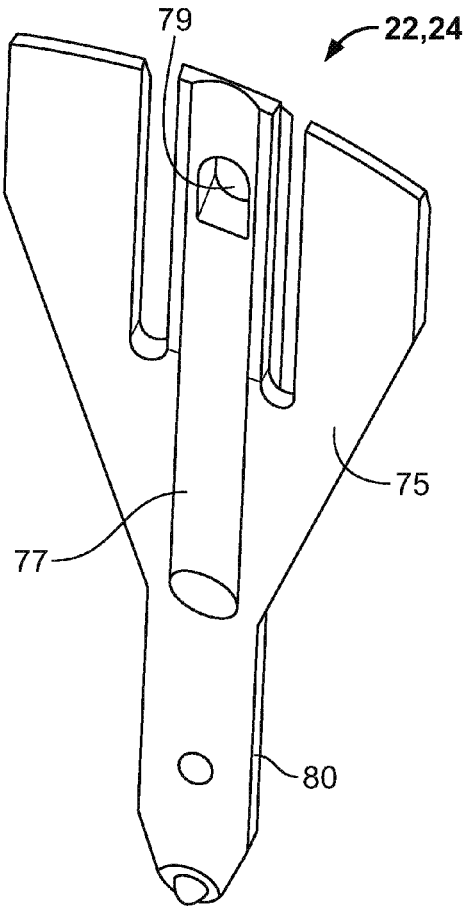

FIG. 4

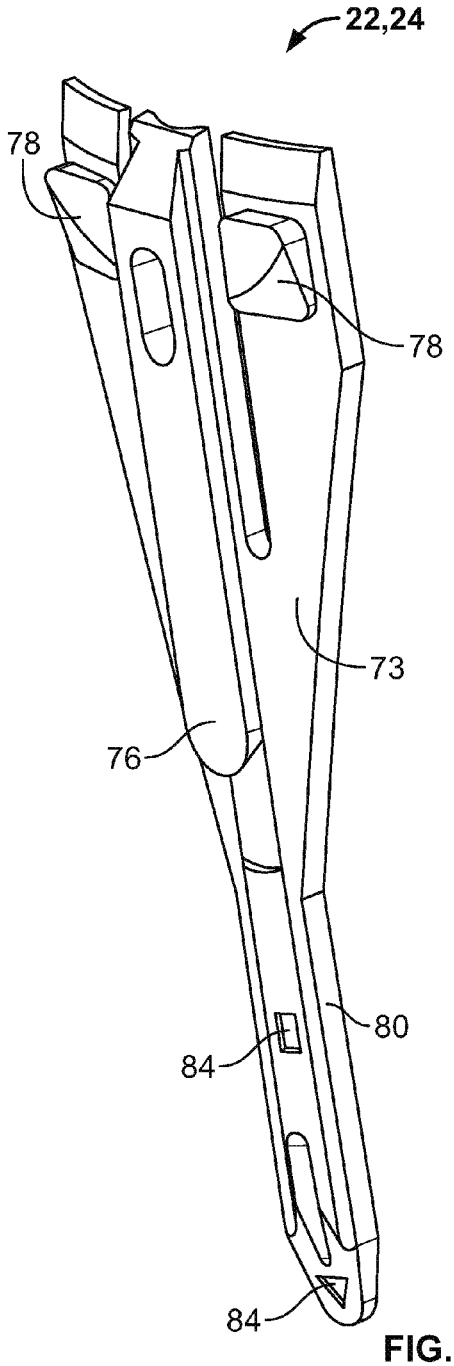

FIG. 5

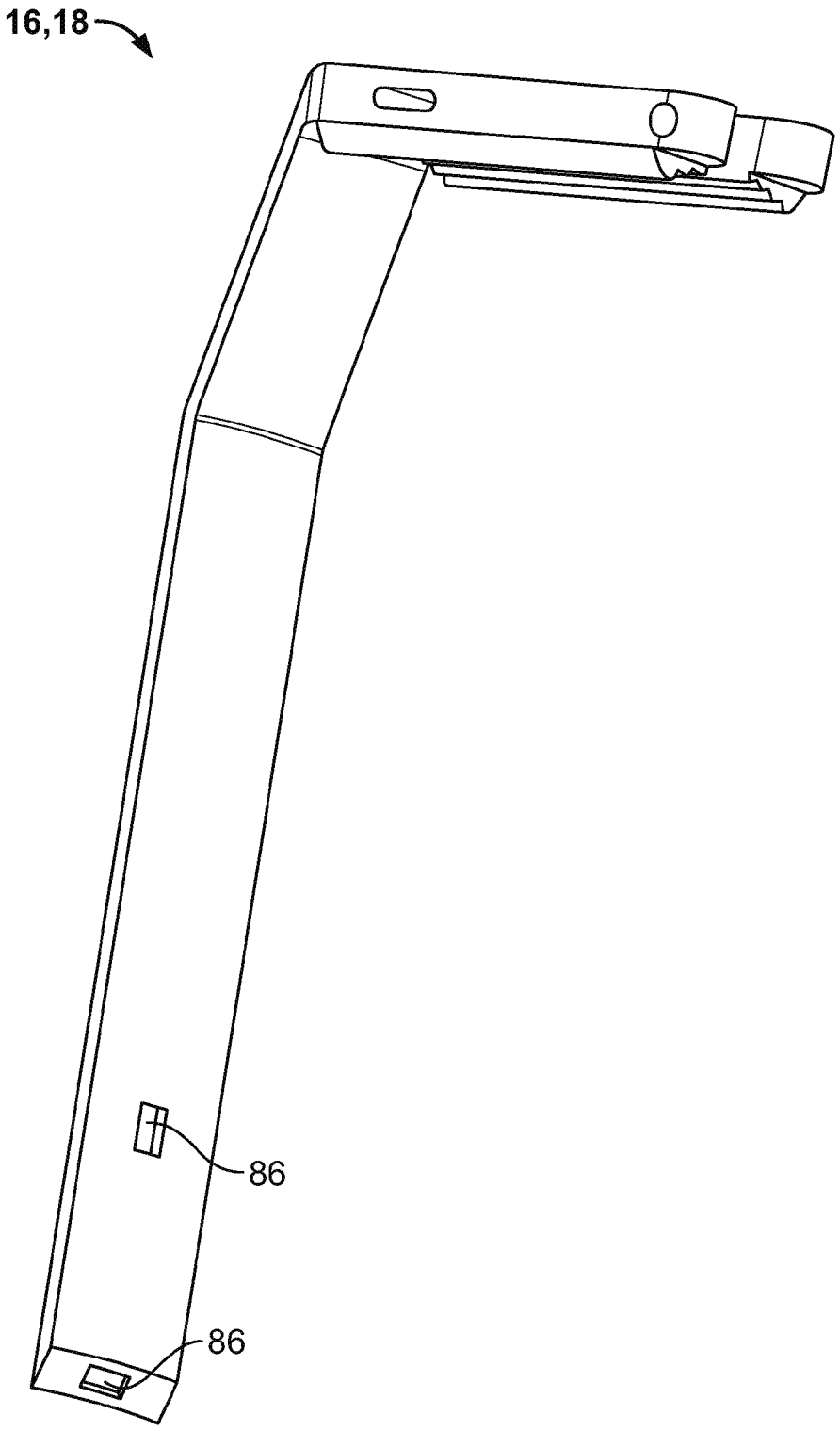

FIG. 6

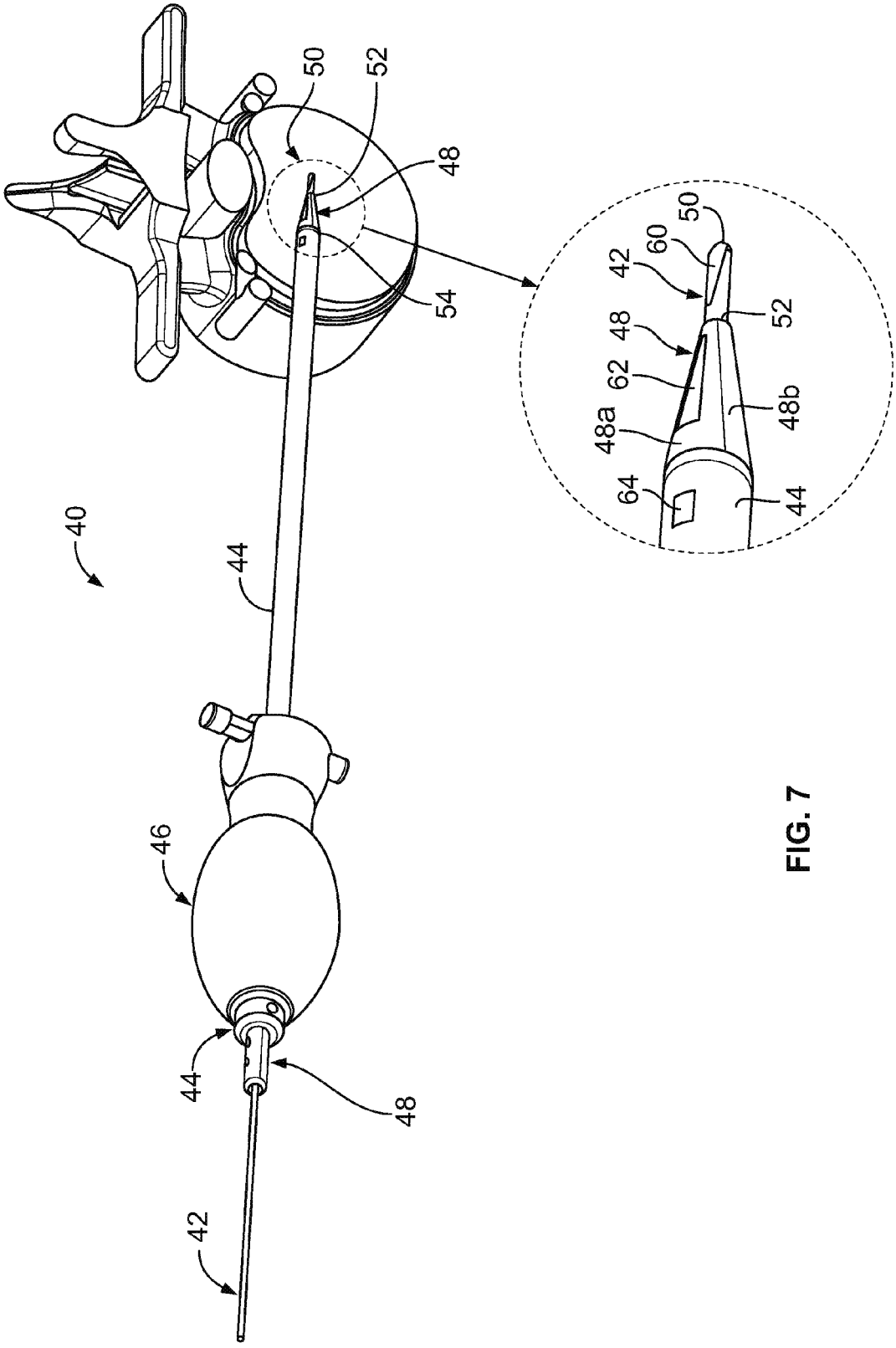

FIG. 7

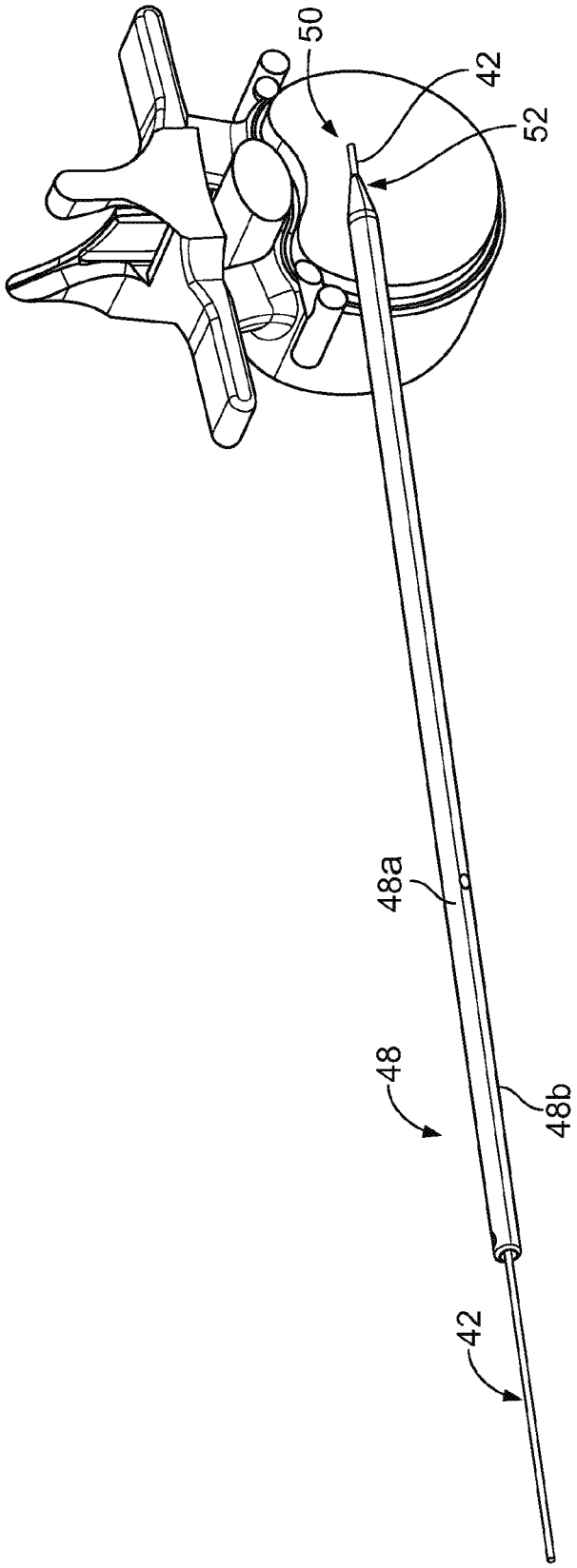

FIG. 8

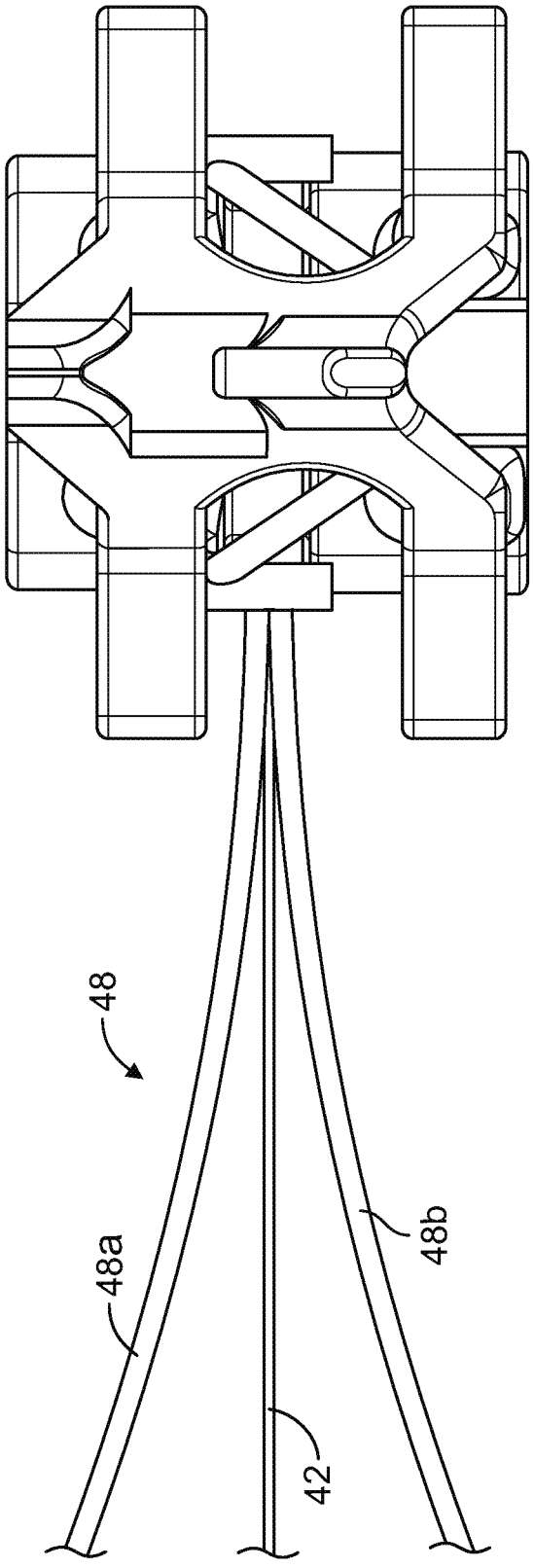

FIG. 9

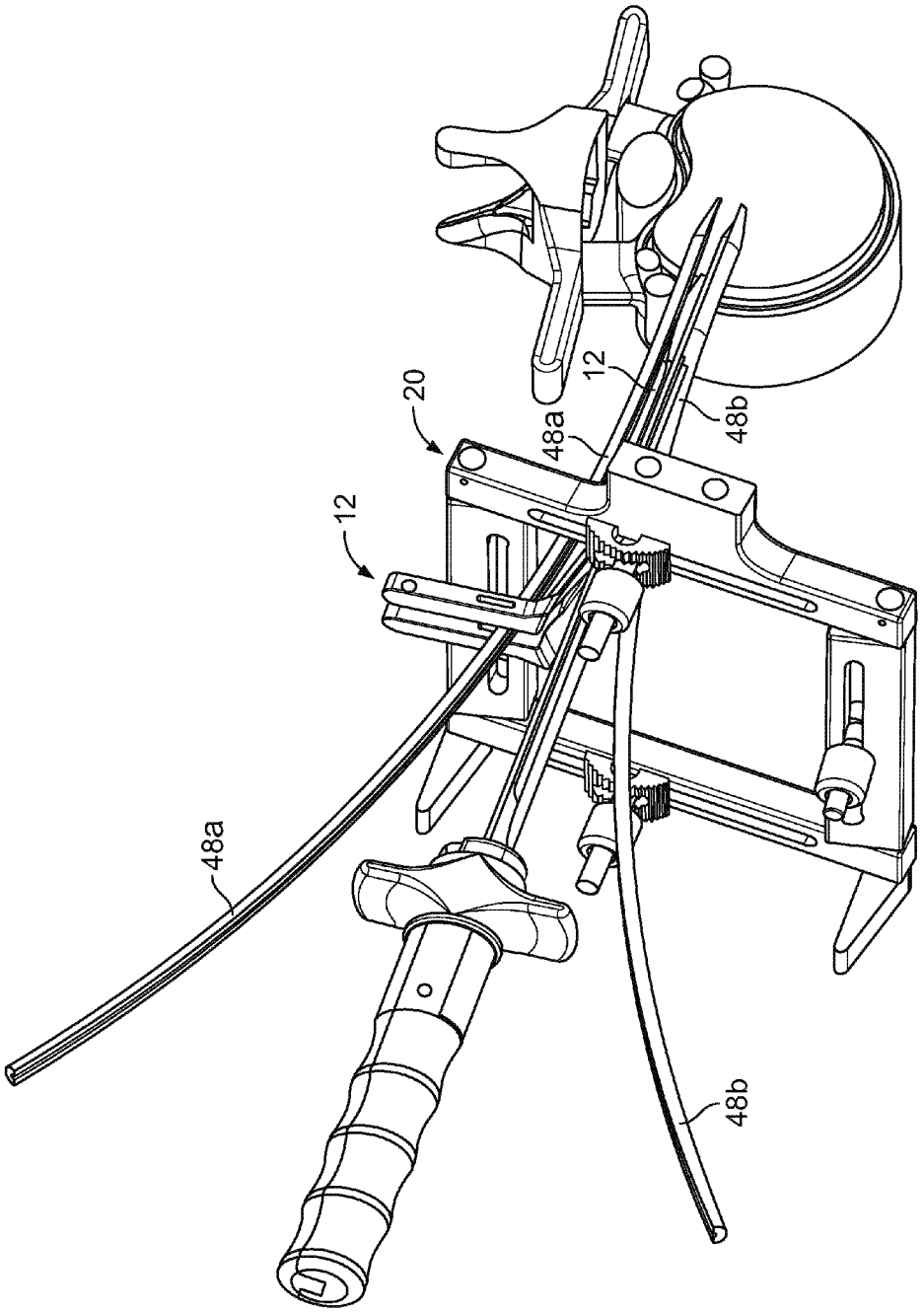

FIG. 10

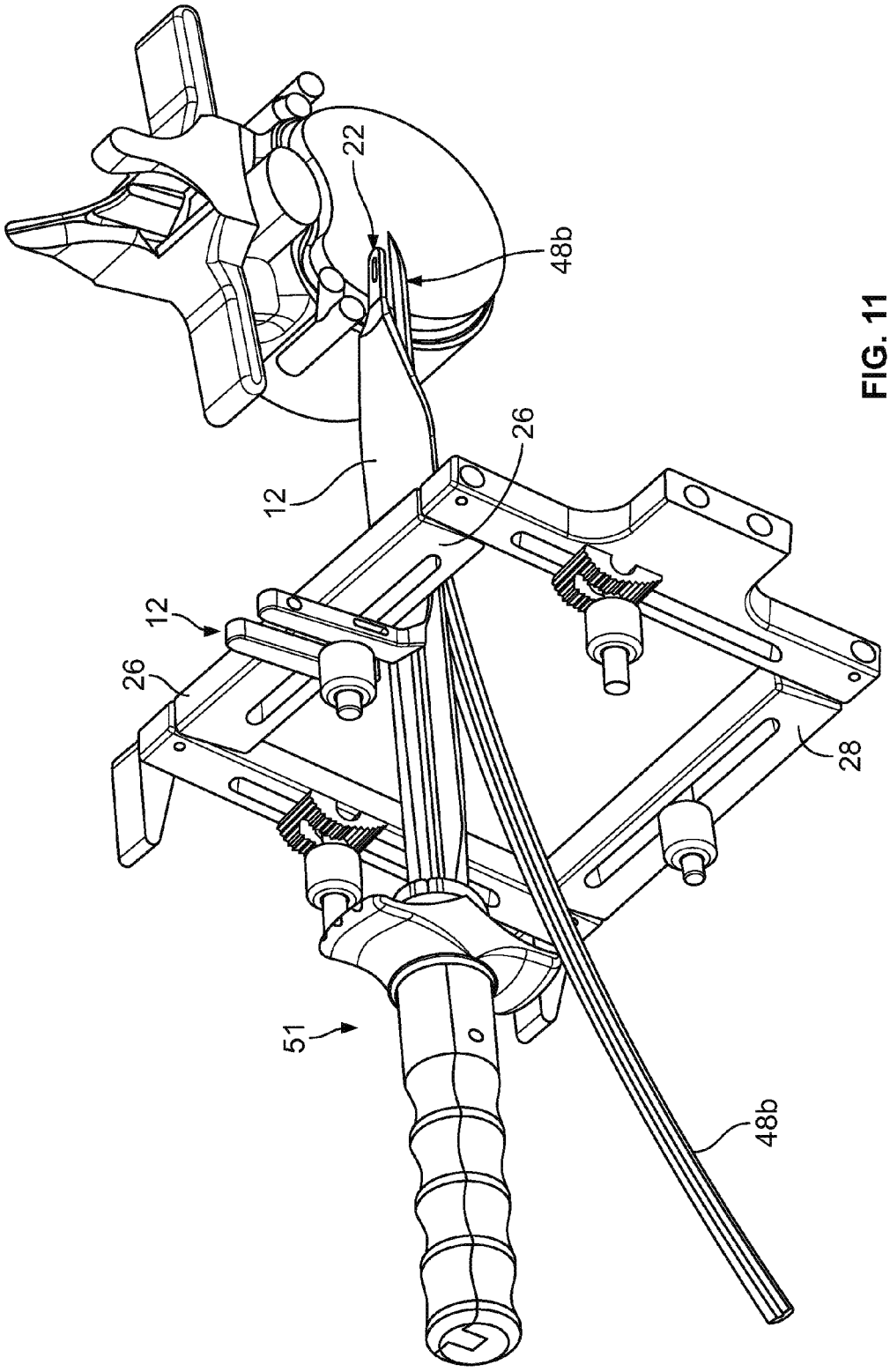

FIG. 11

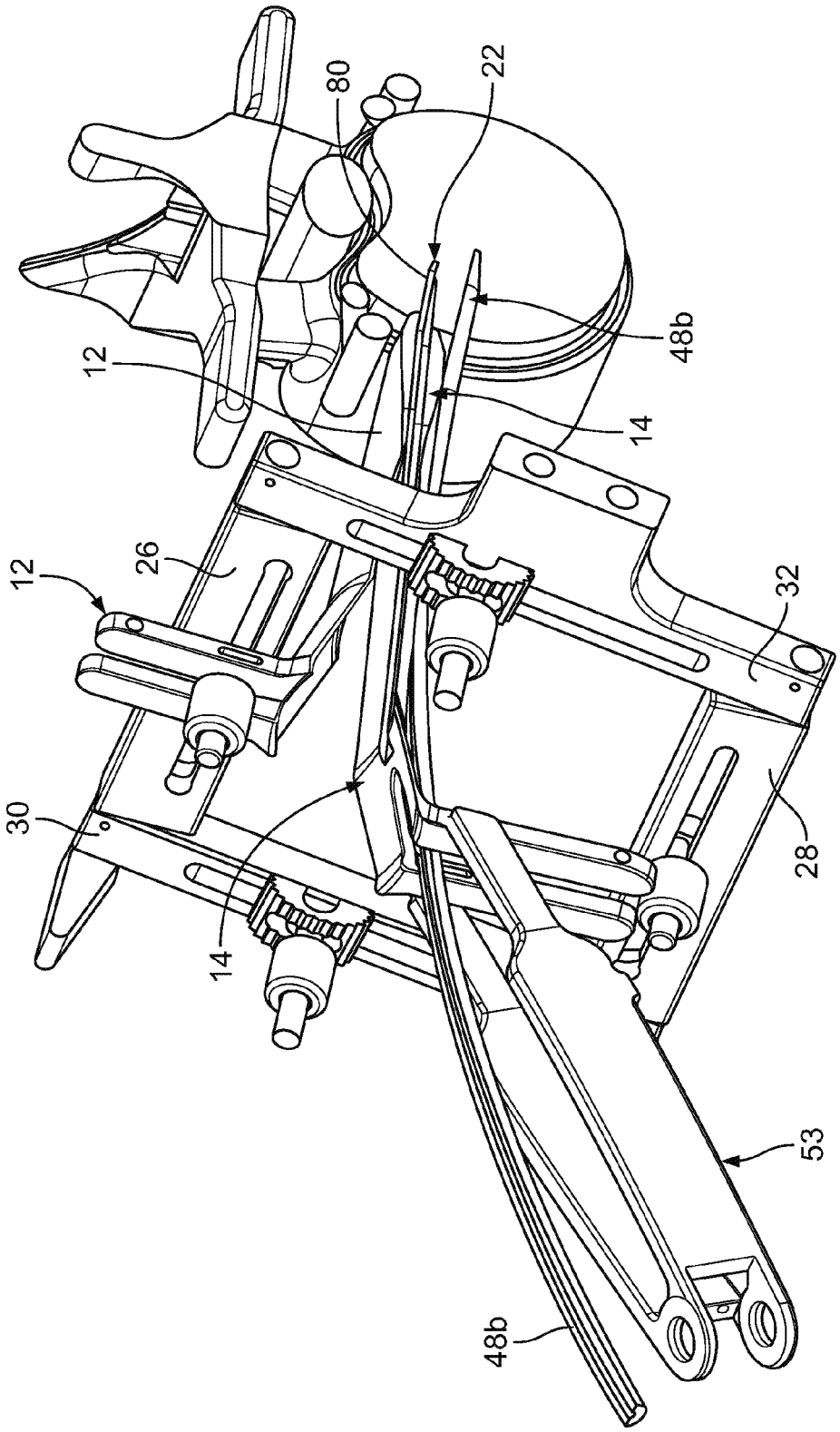

FIG. 12

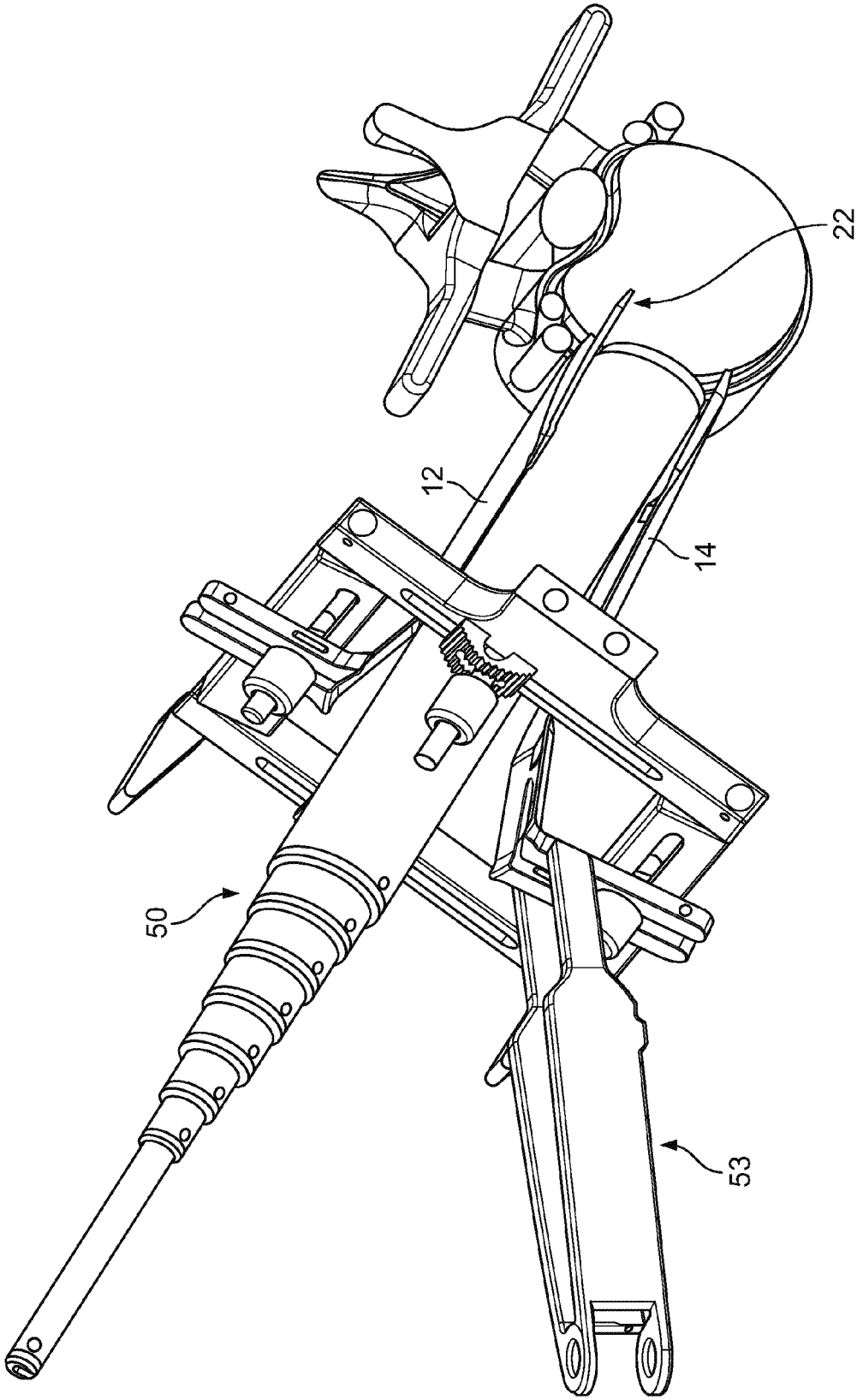

FIG. 13

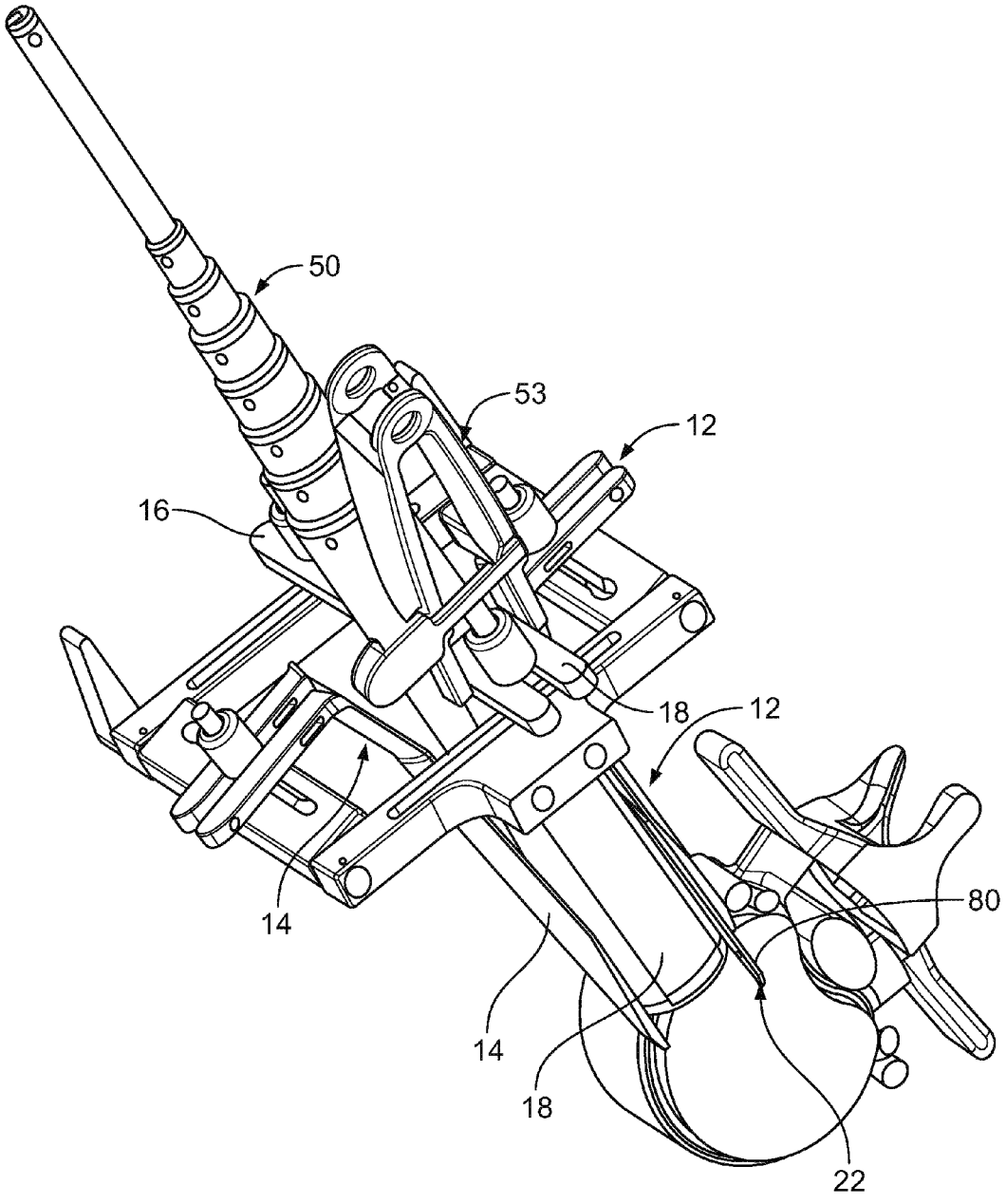

FIG. 14

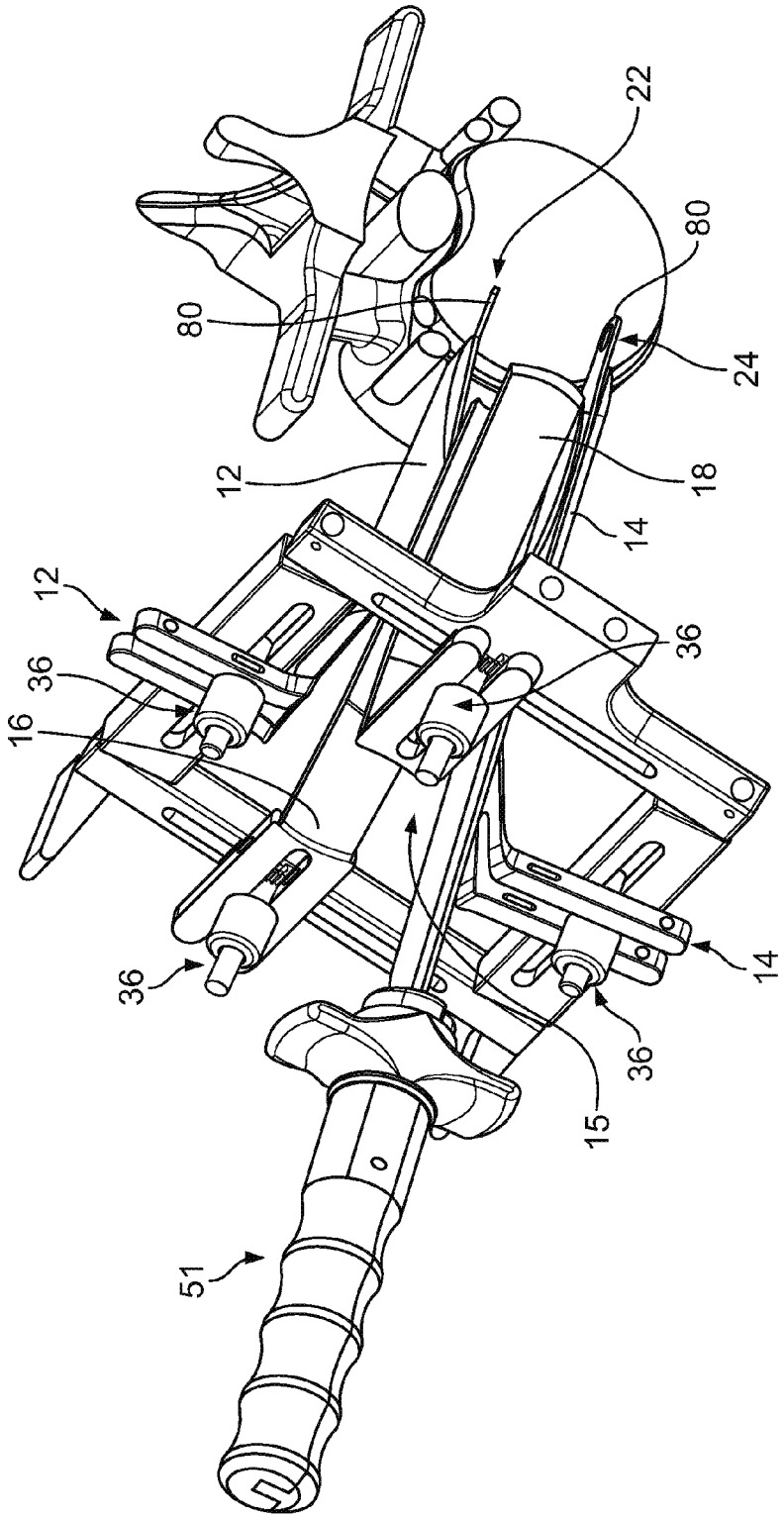

FIG. 15

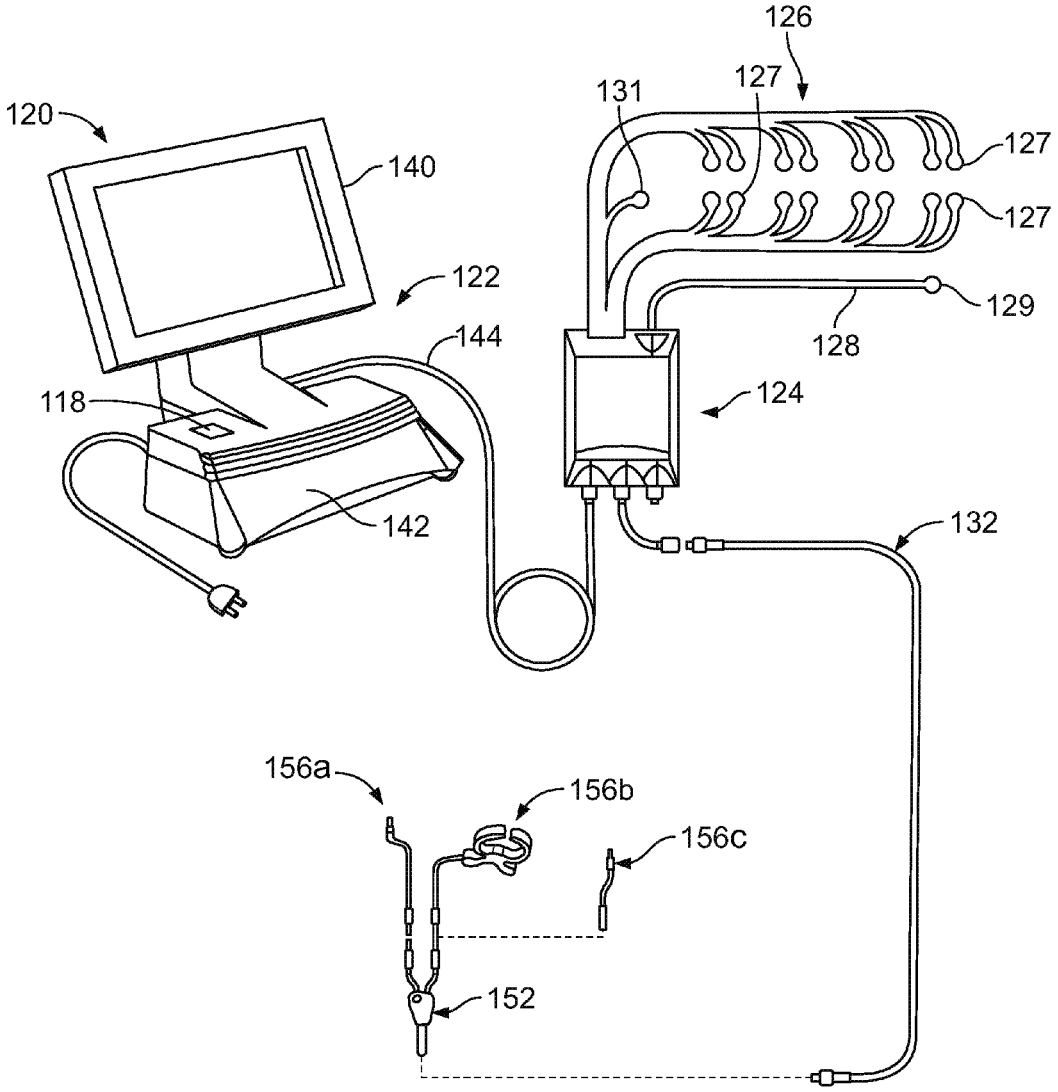
126
127
131
120
140
127
127
122
129
144
128
118
124
142
132
156a
156b
156c
152

FIG. 16

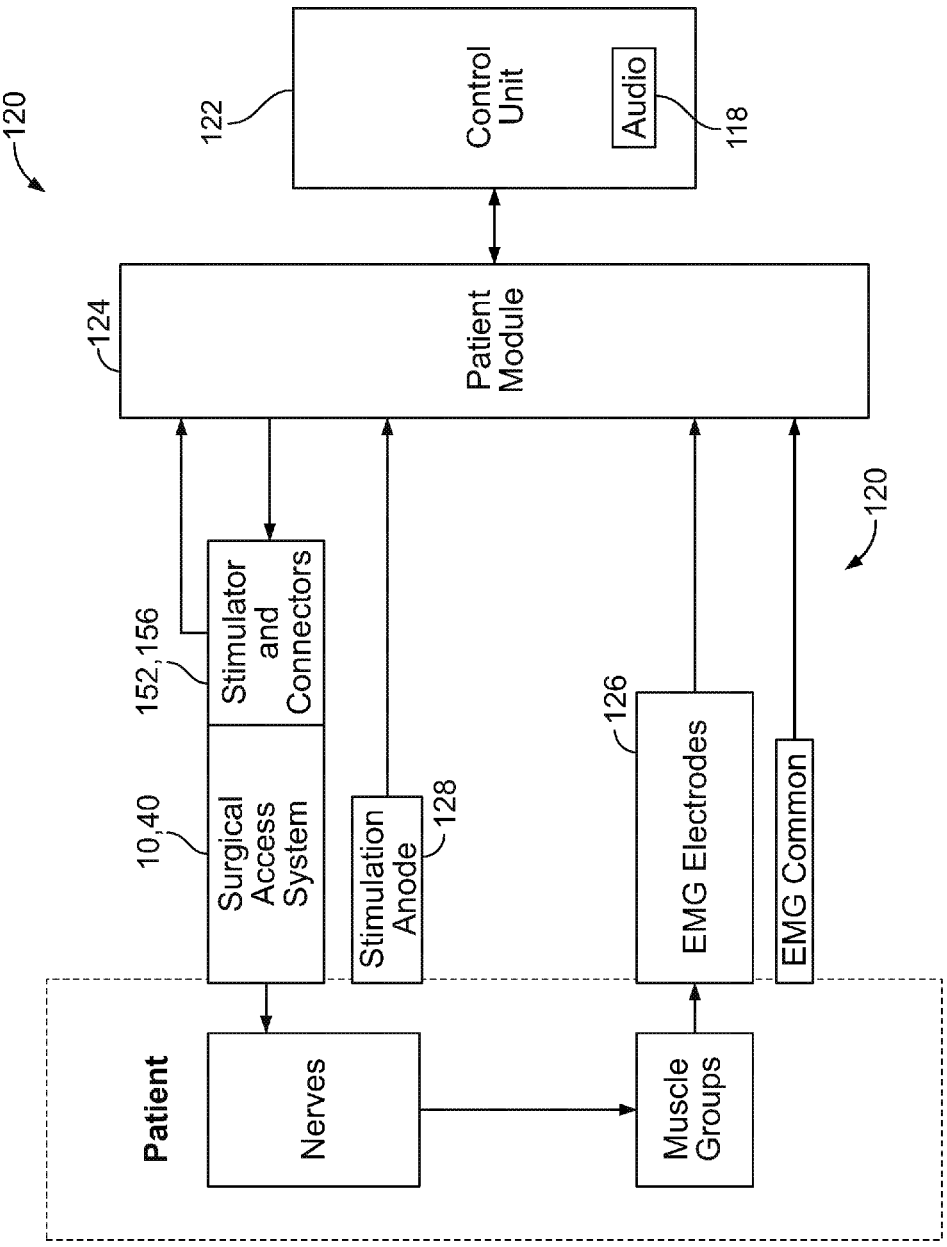
120
122
Control Unit
Audio
118
124
Patient Module
120
152,156
Stimulator and Connectors
10,40
Surgical Access System
Stimulation Anode
128
126
EMG Electrodes
EMG Common
Patient
Nerves
Muscle Groups

FIG. 17

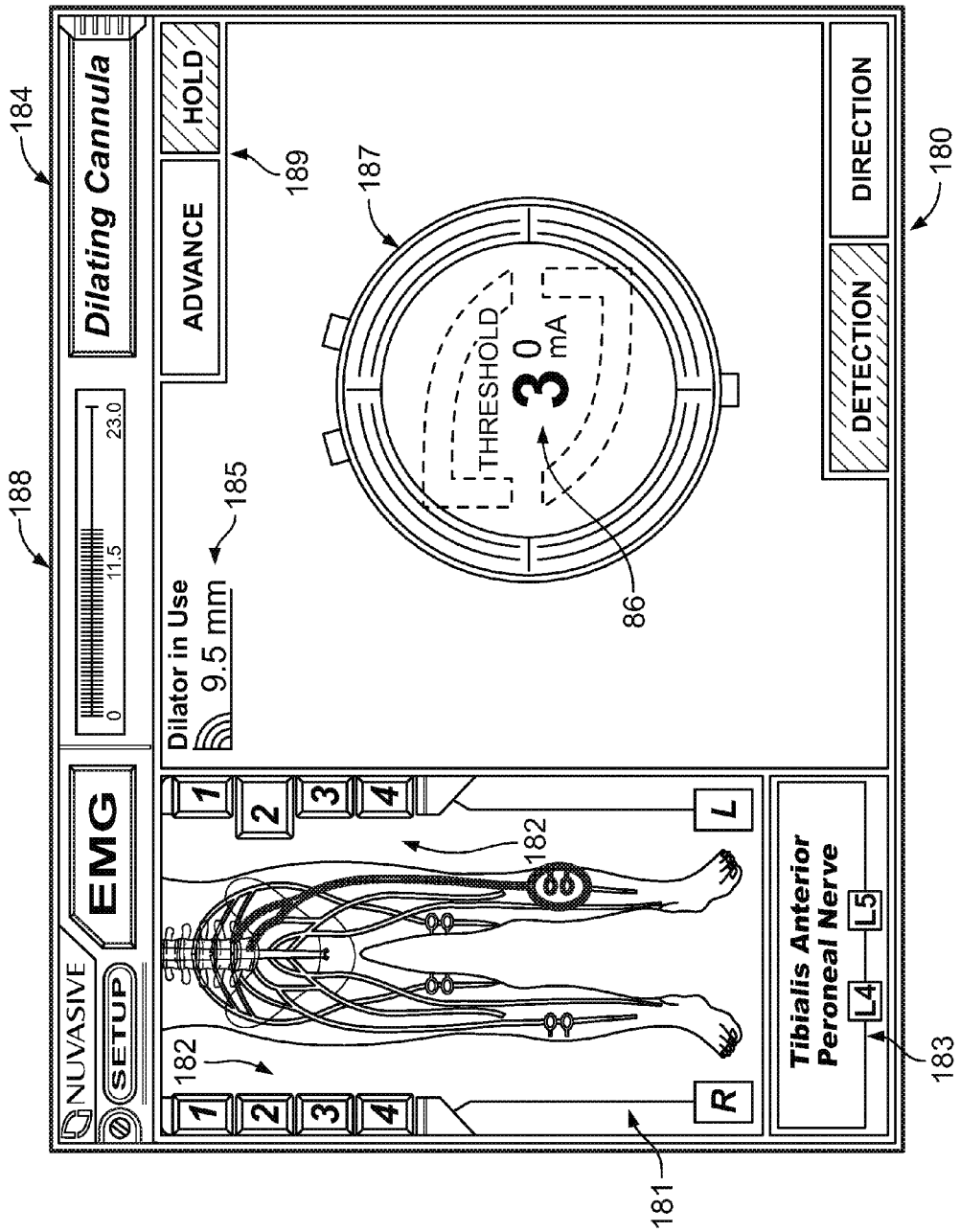
184
188
NUVASIVE
EMG
SETUP
Dilating Cannula
0
11.5
23.0
Dilator in Use
9.5 mm
185
ADVANCE
HOLD
189
187
THRESHOLD
30 mA
86
DETECTION
DIRECTION
180
182
1
2
3
4
L
R
182
181
Tibialis Anterior
Peroneal Nerve
L4
L5
183

FIG. 18

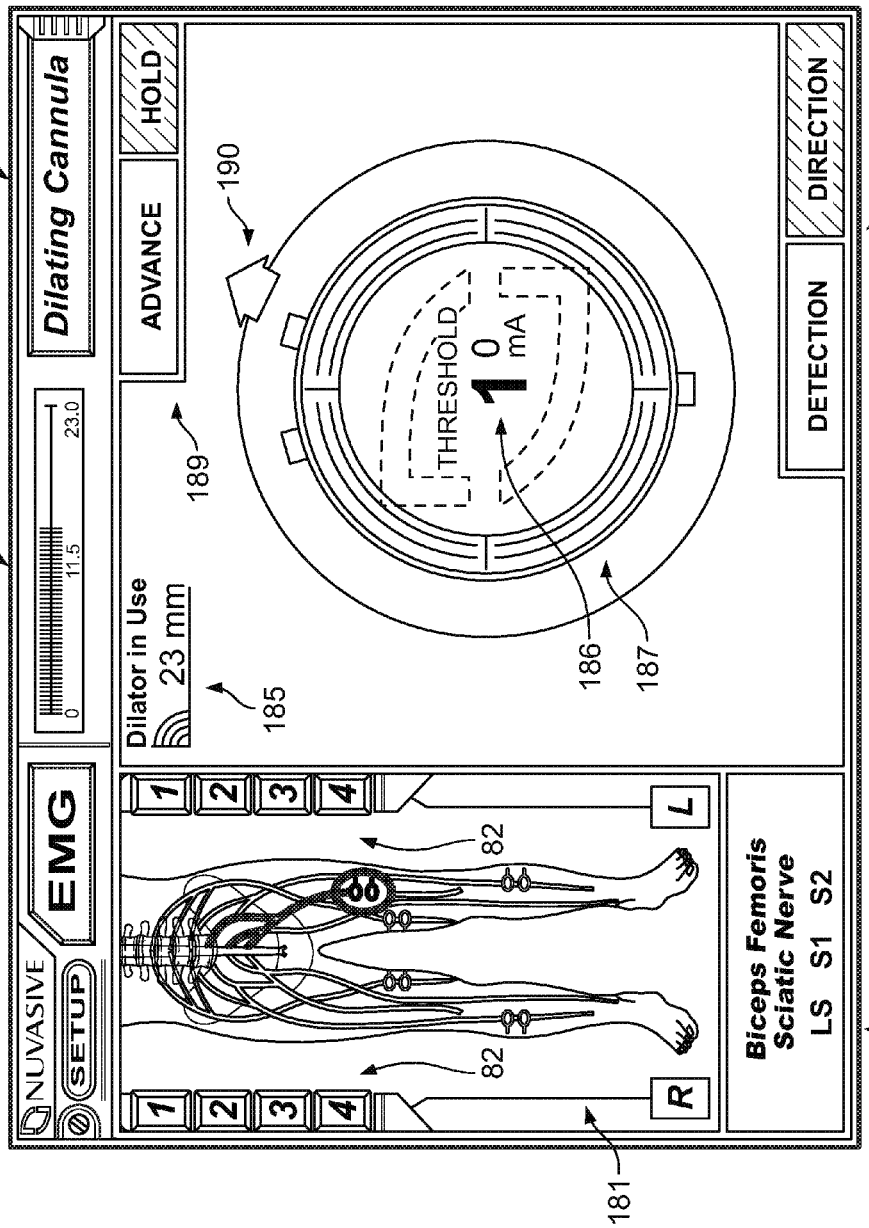
NUVASIVE
SETUP
EMG
Dilating Cannula
0
11.5
23.0
ADVANCE
HOLD
Dilator in Use
23 mm
THRESHOLD
10 mA
DETECTION
DIRECTION
1
2
3
4
L
R
Biceps Femoris
Sciatic Nerve
LS S1 S2
82
82
181
183
184
185
186
187
188
189
190
180

FIG. 19

SURGICAL ACCESS SYSTEM AND RELATED METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/195,227, filed Mar. 3, 2014 (now U.S. Pat. No. 8,956,283), which is a continuation of U.S. patent application Ser. No. 14/018,173, filed Sep. 4, 2013, (now U.S. Pat. No. 8,663,100), which is a continuation of U.S. patent application Ser. No. 13/756,908 filed Feb. 1, 2013 (now U.S. Pat. No. 8,679,006), which is a continuation of U.S. patent application Ser. No. 13/486,093 filed Jun. 1, 2012 (now U.S. Pat. No. 8,512,235), which is a continuation of U.S. patent application Ser. No. 12/650,271 filed Dec. 30, 2009 (now U.S. Pat. No. 8,192,357), which is a continuation of U.S. patent application Ser. No. 10/682,568 filed Oct. 8, 2003 (now U.S. Pat. No. 8,137,284), which claims the benefit of priority from U.S. Provisional Patent Application Ser. No. 60/417,235 filed Oct. 8, 2002, the entire contents of these applications are hereby expressly incorporated by reference into this disclosure as if set forth fully herein. The present application also incorporates by reference the following patent applications in their entireties (collectively, the "NeuroVision Applications"): PCT App. Ser. No. PCT/US02/22247, entitled "System and Methods for Determining Nerve Proximity, Direction, and Pathology During Surgery," filed on Jul. 11, 2002; PCT App. Ser. No. PCT/US02/30617, entitled "System and Methods for Performing Surgical Procedures and Assessments," filed on Sep. 25, 2002; PCT App. Ser. No. PCT/US02/35047, entitled "System and Methods for Performing Percutaneous Pedicle Integrity Assessments," filed on Oct. 30, 2002; PCT App. Ser. No. PCT/US03/02056, entitled "System and Methods for Determining Nerve Direction to a Surgical Instrument," filed Jan. 15, 2003.

BACKGROUND

I. Field

The present invention relates generally to systems and methods for performing surgical procedures and, more particularly, for accessing a surgical target site in order to perform surgical procedures.

II. Description of Related Art

A noteworthy trend in the medical community is the move away from performing surgery via traditional "open" techniques in favor of minimally invasive or minimal access techniques. Open surgical techniques are generally undesirable in that they typically require large incisions and high amounts of tissue displacement to gain access to the surgical target site, which produces concomitantly high amounts of pain, lengthened hospitalization (increasing health care costs), and high morbidity in the patient population. Less-invasive surgical techniques (including so-called "minimal access" and "minimally invasive" techniques) are gaining favor due to the fact that they involve accessing the surgical target site via incisions of substantially smaller size with greatly reduced tissue displacement requirements. This, in turn, reduces the pain, morbidity and cost associated with such procedures. The access systems developed to date, however, fail in various respects to meet all the needs of the surgeon population.

One drawback associated with prior art surgical access systems relates to the ease with which the operative corridor can be created, as well as maintained over time, depending upon the particular surgical target site. For example, when accessing surgical target sites located beneath or behind musculature or other relatively strong tissue (such as, by way of example only, the psoas muscle adjacent to the spine), it has been found that advancing an operative corridor-establishing instrument directly through such tissues can be challenging and/or lead to unwanted or undesirable effects (such as stressing or tearing the tissues). While certain efforts have been undertaken to reduce the trauma to tissue while creating an operative corridor, such as (by way of example only) the sequential dilation system of U.S. Pat. No. 5,792,044 to Foley et al., these attempts are nonetheless limited in their applicability based on the relatively narrow operative corridor. More specifically, based on the generally cylindrical nature of the so-called "working cannula," the degree to which instruments can be manipulated and/or angled within the cannula can be generally limited or restrictive, particularly if the surgical target site is a relatively deep within the patient.

Efforts have been undertaken to overcome this drawback, such as shown in U.S. Pat. No. 6,524,320 to DiPoto, wherein an expandable portion is provided at the distal end of a cannula for creating a region of increased cross-sectional area adjacent to the surgical target site. While this system may provide for improved instrument manipulation relative to sequential dilation access systems (at least at deep sites within the patient), it is nonetheless flawed in that the deployment of the expandable portion may inadvertently compress or impinge upon sensitive tissues adjacent to the surgical target site. For example, in anatomical regions having neural and/or vasculature structures, such a blind expansion may cause the expandable portion to impinge upon these sensitive tissues and cause neural and/or vasculature compromise, damage and/or pain for the patient.

This highlights yet another drawback with the prior art surgical access systems, namely, the challenges in establishing an operative corridor through or near tissue having major neural structures which, if contacted or impinged, may result in neural impairment for the patient. Due to the threat of contacting such neural structures, efforts thus far have largely restricted to establishing operative corridors through tissue having little or substantially reduced neural structures, which effectively limits the number of ways a given surgical target site can be accessed. This can be seen, by way of example only, in the spinal arts, where the exiting nerve roots and neural plexus structures in the psoas muscle have rendered a lateral or far lateral access path (so-called trans-psoas approach) to the lumbar spine virtually impossible. Instead, spine surgeons are largely restricted to accessing the spine from the posterior (to perform, among other procedures, posterior lumbar interbody fusion (PLIF)) or from the anterior (to perform, among other procedures, anterior lumbar interbody fusion (ALIF)).

Posterior-access procedures involve traversing a shorter distance within the patient to establish the operative corridor, albeit at the price of oftentimes having to reduce or cut away part of the posterior bony structures (i.e. lamina, facets, spinous process) in order to reach the target site (which typically comprises the disc space). Anterior-access procedures are relatively simple for surgeons in that they do not involve reducing or cutting away bony structures to reach the surgical target site. However, they are nonetheless disadvantageous in that they require traversing through a much greater distance within the patient to establish the operative corridor, oftentimes requiring an additional surgeon to assist with moving the various internal organs out of the way to create the operative corridor.

The present invention is directed at eliminating, or at least minimizing the effects of, the above-identified drawbacks in the prior art.

SUMMARY

The present invention accomplishes this goal by providing a novel access system and related methods which involve: (1) distracting the tissue between the patient's skin and the surgical target site to create an area of distraction (otherwise referred to herein as a "distraction corridor"); (2) retracting the distraction corridor to establish and maintain an operative corridor; and/or (3) detecting the existence of (and optionally the distance and/or direction to) neural structures before, during and after the establishment of the operative corridor through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient.

As used herein, "distraction" or "distracting" is defined as the act of creating a corridor (extending to a location at or near the surgical target site) having a certain cross-sectional area and shape ("distraction corridor"), and "retraction" or "retracting" is defined as the act of creating an operative corridor by increasing or maintaining the cross-sectional area of the distraction corridor (and/or modifying its shape) with at least one retractor blade such that surgical instruments can be passed through operative corridor to the surgical target site. It is expressly noted that, although described herein largely in terms of use in spinal surgery, the access system of the present invention is suitable for use in any number of additional surgical procedures, including those wherein tissue having significant neural structures must be passed through (or near) in order to establish an operative corridor.

According to one broad aspect of the present invention, the access system comprises a tissue distraction assembly and a tissue retraction assembly. The tissue distraction assembly (in conjunction with one or more elements of the tissue retraction assembly) is capable of, as an initial step, distracting a region of tissue between the skin of the patient and the surgical target site. The tissue retraction assembly is capable of, as a secondary step, being introduced into this distracted region to thereby define and establish the operative corridor. Once established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated within the operative corridor depending upon the given surgical procedure.

The tissue distraction assembly may include any number of components capable of performing the necessary distraction. By way of example only, the tissue distraction assembly may include a K-wire, an initial dilator of split construction, and one or more dilators of traditional (that is, non-split) construction for performing the necessary tissue distraction to receive the remainder of the tissue retractor assembly thereafter. One or more electrodes may be provided on one or more of the K-wire and dilator(s) to detect the presence of (and optionally the distance and/or direction to) neural structures during tissue distraction.

The tissue retraction assembly may include any number of components capable of performing the necessary retraction. By way of example only, the tissue retraction assembly may include one or more retractor blades extending proximally from the surgical target site for connection with a portion (more specifically, a pivot linkage assembly) of the speculum assembly. The retractor blades may be equipped with a mechanism for transporting or emitting light at or near the surgical target site to aid the surgeon's ability to visualize the surgical target site, instruments and/or implants during the given surgical procedure. According to one embodiment, this mechanism may comprise, but need not be limited to, providing one or more strands of fiber optic cable within the walls of the retractor blades such that the terminal (distal) ends are capable of emitting light at or near the surgical target site. According to another embodiment, this mechanism may comprise, but need not be limited to, constructing the retractor blades of suitable material (such as clear polycarbonate) and configuration such that light may be transmitted generally distally through the walls of the retractor blade light to shine light at or near the surgical target site. This may be performed by providing the retractor blades having light-transmission characteristics (such as with clear polycarbonate construction) and transmitting the light almost entirely within the walls of the retractor blade (such as by frosting or otherwise rendering opaque portions of the exterior and/or interior) until it exits a portion along the interior (or medially-facing) surface of the retractor blade to shine at or near the surgical target site. The exit portion may be optimally configured such that the light is directed towards the approximate center of the surgical target site and may be provided along the entire inner periphery of the retractor blade or one or more portions therealong.

The retractor blades may be optionally dimensioned to receive and direct a rigid shim element to augment the structural stability of the retractor blades and thereby ensure the operative corridor, once established, will not decrease or become more restricted, such as may result if distal ends of the retractor blades were permitted to "slide" or otherwise move in response to the force exerted by the displaced tissue. In a preferred embodiment, only the posterior and anterior retractor blades are equipped with such rigid shim elements, which are advanced into the disc space after the posterior and anterior retractor blades are positioned. The rigid shim elements are preferably oriented within the disc space such that they distract the adjacent vertebral bodies, which serves to restore disc height. They are also preferably advanced a sufficient distance within the disc space (preferably past the midline), which serves the dual purpose of preventing post-operative scoliosis and forming a protective barrier (preventing the migration of tissue (such as nerve roots) into the operative field and the inadvertent advancement of instruments outside the operative field).

According to yet another aspect of the present invention, any number of distraction assemblies and/or retraction assemblies (including but not limited to those described herein) may be equipped to detect the presence of (and optionally the distance and/or direction to) neural structures during the steps tissue distraction and/or retraction. To accomplish this, one or more stimulation electrodes are provided on the various components of the distraction assemblies and/or retraction assemblies, a stimulation source (e.g. voltage or current) is coupled to the stimulation electrodes, a stimulation signal is emitted from the stimulation electrodes as the various components are advanced towards the surgical target site, and the patient is monitored to determine if the stimulation signal causes muscles associated with nerves or neural structures within the tissue to innervate. If the nerves innervate, this indicates that neural structures may be in close proximity to the distraction and/or retraction assemblies.

This monitoring may be accomplished via any number of suitable fashions, including but not limited to observing visual twitches in muscle groups associated with the neural structures likely to found in the tissue, as well as any number of monitoring systems. In either situation (traditional EMG or surgeon-driven EMG monitoring), the access system of the present invention may advantageously be used to traverse tissue that would ordinarily be deemed unsafe or undesirable,

thereby broadening the number of manners in which a given surgical target site may be accessed.

BRIEF DESCRIPTION OF THE DRAWINGS

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

FIG. **1** is a perspective view of a tissue retraction assembly (in use) forming part of a surgical access system according to the present invention, including a posterior retractor blade **12**, an anterior retractor blade **14**, and two supplemental retractor blades **16**, **18**;

FIGS. **2** and **3** are front and back views, respectively, of the posterior and anterior retractor blades **12**, **14** shown in FIG. **1**;

FIGS. **4** and **5** are front and back views, respectively, of shim element **22**, **24** according to the present invention, dimensioned to be engaged with the inner surface of the posterior and anterior retractor blades of FIG. **1** for the purpose of positioning a shim extension **80** within the disc space;

FIG. **6** is a perspective view illustrating the back of the supplemental retractor blades **16**, **18** shown in FIG. **1** according to the present invention;

FIG. **7** is a perspective view illustrating the components and use of an initial distraction assembly **40** (i.e. K-wire **42**, an initial dilating cannula **44** with handle **46**, and a split-dilator **48** housed within the initial dilating cannula **44**) forming part of the surgical access system according to the present invention, for use in distracting to a surgical target site (e.g. disk space);

FIG. **8** is a perspective view illustrating the K-wire **42** and split-dilator **48** of the initial distraction assembly **40** with the initial dilating cannula **44** and handle **46** of FIG. **7** removed;

FIG. **9** is a posterior view of the vertebral target site illustrating the split-dilator **48** of the present invention in use distracting in a generally cephalad-caudal fashion according to one aspect of the present invention;

FIG. **10** is a perspective view illustrating the split-dilator **48** of the present invention in use distracting in a generally posterior-anterior fashion according to another aspect of the present invention and in use with a posterior retractor blade **12** forming part of the retractor assembly **10** of the present invention;

FIG. **11** is a perspective view illustrating a shim introducer **51** introducing the posterior shim element **22** such that the shim extension **80** is positioned within the disc space;

FIG. **12** is a perspective view illustrating an anterior retractor blade **14** forming part of the retractor assembly **10** of the present invention being introduced with a gripping assembly **53** in association with the anterior half **48***b* of the split dilator **48** of the present invention;

FIG. **13** is a perspective view of the anterior retractor blade **14** being moved away from the posterior retractor blade **12** through the use of a plurality of sequentially dilating cannula **50**;

FIG. **14** is a perspective view illustrating the introduction of supplemental retractor blades **16**, **18** according to the present invention;

FIG. **15** is a perspective view illustrating a shim introducer **51** introducing the anterior shim element **24** such that the shim extension **80** is positioned within the disc space;

FIG. **16** is a perspective view of an exemplary nerve monitoring system capable of performing nerve monitoring before, during and after the creating of an operative corridor to a surgical target site using the surgical access system in accordance with the present invention;

FIG. **17** is a block diagram of the nerve monitoring system shown in FIG. **16**; and

FIGS. **18-19** are screen displays illustrating exemplary features and information communicated to a user during the use of the nerve monitoring system of FIG. **16**.

DETAILED DESCRIPTION

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. The surgical access system disclosed herein boasts a variety of inventive features and components that warrant patent protection, both individually and in combination.

It is furthermore to be readily understood that, although discussed below primarily within the context of spinal surgery, the surgical access system and related methods of the present invention may find applicability in any of a variety of surgical and/or medical applications such that the following description relative to the spine is not to be limiting of the overall scope of the present invention. Moreover, while described below employing the nerve monitoring features described above (otherwise referred to as "nerve surveillance") during spinal surgery, it will be appreciated that such nerve surveillance will not be required in all situations, depending upon the particular surgical target site (e.g. disk space, vertebral body, and/or internal organ) and surgical approach (e.g. lateral, posterior, anterior, and/or postero-lateral approaches to the spine).

The present invention is directed at a novel surgical access system and related methods which involve creating and maintaining an operative corridor to the surgical target site, and optionally detecting the existence of (and optionally the distance and/or direction to) neural structures before, during and/or after this process (including the steps of distraction and/or retraction).

Distraction followed by retraction is advantageous because it provides the ability to more easily position an operative corridor-establishing device through tissue that is strong, thick or otherwise challenging to traverse in order to access a surgical target site. The various distraction systems of the present invention are advantageous in that they provide an improved manner of atraumatically establishing a distraction corridor prior to the use of the retraction systems of the present invention. The various retractor systems of the present invention are advantageous in that they provide an operative corridor having improved cross-sectional area and shape (including customization thereof) relative to the prior art surgical access systems. Moreover, by optionally equipping the various distraction systems and/or retraction systems with one or more electrodes, an operative corridor may be established through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient.

The present invention involves accessing a surgical target site in a fashion less invasive than traditional "open" surgeries and doing so in a manner that provides access in spite of the neural structures required to be passed through (or near) in

order to establish an operative corridor to the surgical target site. Generally speaking, the surgical access system of the present invention accomplishes this by providing a tissue distraction assembly and a tissue retraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures. These electrodes are preferably provided for use with a nerve surveillance system such as, by way of example, the type shown and described in the NeuroVision Applications referenced above, the entire contents of which are expressly incorporated by reference as if set forth herein in their entirety.

Generally speaking, this nerve surveillance is capable of detecting the existence of (and optionally the distance and/or direction to) neural structures during the distraction and retraction of tissue by detecting the presence of nerves by applying a stimulation signal to such instruments and monitoring the evoked EMG signals from the myotomes associated with the nerves being passed by the distraction and retraction systems of the present invention. In so doing, the system as a whole (including the surgical access system of the present invention) may be used to form an operative corridor through (or near) any of a variety of tissues having such neural structures, particularly those which, if contacted or impinged, may otherwise result in neural impairment for the patient. In this fashion, the access system of the present invention may be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

The tissue distraction assembly of the present invention (comprising a K-wire, an initial dilator, and a split-dilator disposed within the initial dilator) is employed to distract the tissues extending between the skin of the patient and a given surgical target site (preferably along the posterior region of the target intervertebral disc) such that, once distracted, the resulting void or distracted region within the patient is of sufficient size to accommodate the introduction of a posterior retractor blade forming part of a tissue retraction assembly of the present invention. This forms the posterior border of the resulting operative corridor. Following (or contemporaneous with) this, a posterior shim element (which is preferably slideably engaged with the posterior retractor blade) may be advanced such that a shim extension in positioned within the posterior region of the disc space. An anterior retractor blade may then be introduced (in generally abutting relation with the posterior retractor blade) and thereafter moved anteriorly to increase the AP (or "width") dimension of the operative corridor. Once in the appropriate anterior position, the anterior retractor blade may be locked in position and, thereafter, an anterior shim element advanced therealong for positioning a shim extension within the anterior of the disc space. The shim elements serve to distract the adjacent vertebral bodies (thereby restoring disc height), to form protective barriers (against the migration of tissue into (or instruments out of) the operative site), and to rigidly couple the posterior and anterior retractor blades in fixed relation relative to the vertebral bodies. First and second supplemental retractor blades (disposed caudal and cephalad) are also preferably employed to establish and maintain the "height" dimension of the operative corridor. Once established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated within the operative corridor depending upon the given surgical procedure.

FIG. **1** illustrates a tissue retraction assembly **10** forming part of a surgical access system according to the present invention. The retraction assembly **10** includes a posterior retractor blade **12**, an anterior retractor blade **14**, and supplemental retractor blades **16**, **18**, all of which are coupled to a mounting structure **20**. Posterior and anterior retractor blades **12**, **14** establish an AP (or "width") dimension of an operative corridor **15**. Posterior retractor blade **12** and anterior retractor blade **14** are equipped with shim elements **22**, **24**, respectively. Shim elements **22**, **24** serve to distract the adjacent vertebral bodies (thereby restoring disc height), form protective barriers (against the migration of tissue into (or instruments out of) the operative site), and rigidly couple the posterior and anterior retractor blades **12**, **14** in fixed relation relative to the vertebral bodies. First and second supplemental retractor blades **16**, **18** (disposed caudal and cephalad) establish and maintain the "height" dimension of the operative corridor **15**.

Any number of suitable mounting units (not shown) may be employed to maintain the retraction assembly **10** in a fixed and rigid fashion relative to the patient. The mounting structure **20** may be coupled to any number of mechanisms for rigidly registering the mounting structure **20** in fixed relation to the operative site, such as through the use of an articulating arm mounted to the operating table. The mounting structure **20** includes posterior and anterior struts **26**, **28** disposed in hinged relation to fixed strut members **30**, **32**. The hinged nature of struts **26**, **28** allows the posterior and anterior retractor blades **12**, **14** to be adjusted independently of one another. The proximal portion of each of the retractor blades **12-18** is preferably provided in a split or forked fashion to accommodate locking assemblies **36** for locking the position of the retractor blades **12-18** with respect to the mounting assembly **20**.

The retractor blades **12**, **14** (FIGS. **2-3**) are dimensioned to detachably couple with the shim elements **22**, **24** (FIGS. **4-5**), respectively. In one embodiment, shown best in FIG. **3**, this is accomplished by providing the inner surface **72** of each retractor blade **12**, **14** with an engagement groove **70** (having, by way of example, a female dove-tail configuration as shown) along the midline thereof and one or more recess **74** disposed at or near the distal end. As best seen in FIG. **5**, the exterior surface **73** of each shim element **22**, **24** is provided with an elongated engagement member **76** (having, by way of example, a male dove-tail configuration as shown) dimensioned to be slideably received within the engagement groove **70** of the retractor blades **12**, **14**, along with a pair of generally square-shaped engagement members **78** dimensioned to "snap" into the recesses **74** disposed at the distal ends of the retractor blades **12**, **14**.

The inner surface **75** of each shim elements **22**, **24** (FIG. **4**) is provided with a generally concave region **77** having an aperture **79** formed therein for engagement with a shim introducer (shown generally in FIGS. **11** and **15**) for the purpose of controlling the engagement between the shim elements **22**, **24** and the retractor blades **12**, **14**, respectively, as well as the advancement of the distal regions **80** of the shim elements **22**, **24** into the surgical target site (e.g. disc space). As best seen in FIGS. **2** and **5**, the retractor blades **12**, **14** and shim elements **22**, **24** may be respectively provided with one or more electrodes **82**, **84** for use in undertaking the nerve surveillance techniques described herein. The same is true for supplemental retractor blades **16**, **18** (FIG. **6**), which may also be provided with one or more electrodes **86** for use in undertaking the nerve surveillance techniques described herein.

The retractor blades **12-18**, as well as the shim elements **22**, **24** may optionally be equipped with any number of different mechanisms for transporting or emitting light at or near the surgical target site to aid the surgeon's ability to visualize the surgical target site, instruments and/or implants during the given surgical procedure. For example, one or more strands of

fiber optic cable may be coupled to these components such that light may be delivered from a light source and selectively emitted into the operative corridor and/or the surgical target site.

This may be accomplished, by way of example only, by constructing the retractor blades **12-18** and/or shim elements **22**, **24** of suitable material (such as clear polycarbonate) and configuration such that light may be transmitted generally distally through a light exit region formed along the entire inner periphery thereof and located in the general vicinity as the operative corridor **15**. This may be performed by providing the retractor blades **12-18** and/or the shim elements **22**, **24** with light-transmission characteristics (such as with clear polycarbonate construction) and transmitting the light almost entirely within the walls of the retractor blades **12-18** and/or shim elements **22**, **24** (such as by frosting or otherwise rendering opaque portions of the exterior and/or interior and coupling the light source thereto such as via a port) until it exits a portion along the interior surface thereof to shine at or near the surgical target site.

In one embodiment, a variety of sets of retractor blades **12-18** and/or shim elements **22**, **24** may be provided, each having a different length to account for any number of possible surgical target sites and/or anatomical configurations. In a further embodiment, each set of retractor blades **12-18** and/or shim elements **22**, **24** may be marked or color-coded to aid in indicating to the surgeon the particular length of the blade **12-18** and/or shim element **22**, **24** (and/or extension **80** of the shim elements **22**, **24**) and/or the depth of the surgical target site.

The retractor blades **12-18** and shim elements **22**, **24** may be constructed from any number of materials suitable for medical applications, including but not limited to plastics, metals, ceramics or any combination thereof. Depending on the construction, some or all of these devices may be disposable (i.e. single use) and/or reusable (i.e. multi-use).

FIG. **7** illustrates an initial distraction assembly **40** forming part of the surgical access system according to the present invention. The initial tissue distraction assembly **40** is employed to perform an initial distraction of tissue from the skin of the patient down to or near the surgical target site, prior to the introduction of the tissue retraction assembly **10** shown and described above with reference to FIGS. **1-6**. By way of example, this is accomplished by providing the initial distraction assembly **40** as including a K-wire **42**, an initial dilating cannula **44** with handle **46**, and a split-dilator **48** housed within the initial dilating cannula **44**. The initial tissue distraction assembly **40** may be constructed from any number of materials suitable for medical applications, including but not limited to plastics, metals, ceramics or any combination thereof. Depending on the construction, some or all of the tissue distraction assembly **40** may be disposable (i.e. single use) and/or reusable (i.e. multi-use). As will be discussed below in greater detail), the K-wire **42**, initial dilating cannula **44**, and split-dilator **48** may be provided with electrodes **60**, **62**, **64**, respectively, for the purpose of determining the location of nerves or neural structures relative to these components as they are advanced towards or positioned at or near the surgical target site.

The K-wire **42** is preferably constructed having generally narrow diameter (such as, by way of example only, 1.5 mm) and sufficient rigidity and strength such that it can pierce the skin of the patient and be advanced through the intervening tissue to reach the surgical target site. The K-wire **42** also preferably includes indicia for determining the distance between a distal end thereof and the skin of the patient. The split-dilator **48** and dilating cannula **44** are inner and outer dilating elements, respectively, capable of being simultaneously introduced over the K-wire **42** for the purpose of further distracting the tissue previously distracted by the K-wire **42**.

The split-dilator **48** is preferably constructed having an inner diameter approximating the diameter of the K-wire **42** (such as, by way of example only, 1.5 mm), an outer diameter of increased dimension (such as, by way of example only, 6.5 mm), and indicia for determining the distance between a distal end **52** and the skin of the patient. The initial dilating cannula **44** is similarly preferably constructed having an inner diameter approximating the outer diameter of the split-dilator **48** (such as, by way of example only, 6.5 mm), an outer diameter of increased dimension (such as, by way of example only, 7.5 mm), and indicia for determining the distance between a distal end **54** and the skin of the patient. The respective lengths of the K-wire **42**, dilating cannula **44**, and split-dilator **48** may vary depending upon the given surgical target site (that is, the "depth" of the surgical target site within the patient). It will be similarly appreciated that the diameters and dimensions for these elements may also vary depending upon the particular surgical procedure. All such surgically appropriate variations (length, diameter, etc. . . .) are contemplated as falling within the scope of the present invention.

In use, the K-wire **42** and split-dilator **48** are disposed within the initial dilating cannula **44** and the entire assembly **40** advanced through the tissue towards the surgical target site (e.g. disk space) as shown in FIG. **7**. After the initial dilating assembly **40** is advanced such that the distal ends of the split-dilator **48** and initial dilating cannula **44** are positioned within the disc space (FIG. **7**), the initial dilator **44** and handle **46** are removed (FIG. **8**) to thereby leave the split-dilator **48** and K-wire **42** in place. As shown in FIG. **9**, the split-dilator **48** is thereafter split such that the respective halves **48***a*, **48***b* are separated from one another to distract tissue in a generally cephalad-caudal fashion relative to the target site. The split dilator **48** may thereafter be relaxed (allowing the dilator halves **48***a*, **48***b* to come together) and rotated such that the dilator halves **48***a*, **48***b* are disposed in the anterior-posterior plane. Once rotated in this manner, the dilator halves **48***a*, **48***b* are again separated to distract tissue in a generally anterior-posterior fashion.

As shown in FIG. **10**, the posterior retractor blade **12** is thereafter advanced along the posterior half **48***a* of the split dilator **48**. At this point, the posterior shim element **22** (FIGS. **4-5**) may be advanced along the posterior retractor blade **12** (FIGS. **2-3**) such that the shim extension **80** (distal end) is positioned in the posterior region of the disc space as shown in FIG. **11** (with posterior half **48***a* of the split dilator **48** removed). The anterior retractor blade **14** may thereafter be advanced along the anterior half **48***b* of the split dilator **48** as shown in FIG. **12**. At this point, secondary distraction may be undertaken according to the present invention by removing the anterior half **48***b* of the split dilator **48** and introducing a plurality of sequentially dilating cannula **50** between the posterior retractor blade **12** and the anterior retractor blade **14** as shown in FIG. **14**. This serves to move the anterior retractor blade **14** anteriorly from the posterior retractor blade **12**.

The retraction of the present invention is performed by expanding, modifying, and/or maintaining the distraction corridor to establish and/or maintain an operative corridor to the surgical target site. As shown in FIG. **15**, according to one embodiment, this is accomplished by introducing the anterior shim element **24** along the anterior retractor blade **14** such that the shim extension **80** (distal region thereof) extends into the anterior region of the disc space. Supplemental retractor blades **16-18** (FIG. **6**) may also optionally be introduced to

define the cephalad and caudal sides of the operative corridor **15** as shown in FIGS. **14-15**. Once positioned as such, the retractor blades **12**, **14** and supplemental retractor blades **16**, **18** may be locked in a position relative to the mounting structure **20** by tightening the respective nuts of the locking assemblies **36**.

The retraction assembly **10** of the present invention, and in particular the shim extensions **80** of the posterior and anterior shim elements **22**, **24** serve to prevent the ingress of unwanted or sensitive biological structures (e.g., nerve roots and/or vasculature) into the surgical target site, as well as prevent instruments from passing outside the surgical target site and contacting surrounding tissues or structures. Once established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated within the operative corridor **15** depending upon the given surgical procedure.

According to yet another aspect of the present invention, any number of distraction components and/or retraction components (including but not limited to those described herein) may be equipped to detect the presence of (and optionally the distance and/or direction to) neural structures during the steps tissue distraction and/or retraction. This is accomplished by employing the following steps: (1) one or more stimulation electrodes are provided on the various distraction and/or retraction components; (2) a stimulation source (e.g. voltage or current) is coupled to the stimulation electrodes; (3) a stimulation signal is emitted from the stimulation electrodes as the various components are advanced towards or maintained at or near the surgical target site; and (4) the patient is monitored to determine if the stimulation signal causes muscles associated with nerves or neural structures within the tissue to innervate. If the nerves innervate, this may indicate that neural structures may be in close proximity to the distraction and/or retraction components.

Neural monitoring may be accomplished via any number of suitable fashions, including but not limited to observing visual twitches in muscle groups associated with the neural structures likely to found in the tissue, as well as any number of monitoring systems, including but not limited to any commercially available "traditional" electromyography (EMG) system (that is, typically operated by a neurophysiologist. Such monitoring may also be carried out via the surgeon-driven EMG monitoring system shown and described in the following commonly owned and co-pending "NeuroVision Applications" incorporated by reference into this disclosure above. In any case (visual monitoring, traditional EMG and/or surgeon-driven EMG monitoring), the access system of the present invention may advantageously be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

FIGS. **16-17** illustrate, by way of example only, a monitoring system **120** of the type disclosed in the NeuroVision Applications suitable for use with the surgical access system of the present invention. The monitoring system **120** includes a control unit **122**, a patient module **124**, and an EMG harness **126** and return electrode **128** coupled to the patient module **124**, and a cable **132** for establishing electrical communication between the patient module **124** and the surgical access system of the present invention. More specifically, this electrical communication can be achieved by providing, by way of example only, a hand-held stimulation controller **152** capable of selectively providing a stimulation signal (due to the operation of manually operated buttons on the hand-held stimulation controller **152**) to one or more connectors **156***a*, **156***b*, **156***c*. The connectors **156***a*, **156***b*, **156***c* are suitable to establish electrical communication between the hand-held stimulation controller **152** and (by way of example only) the stimulation electrodes on the K-wire **42**, the dilating cannula **44**, the split-blade dilator **48**, the retractor blades **12-18**, and/or the shim elements **22**, **24** (collectively "Surgical Access Instruments").

In order to use the monitoring system **120**, then, these Surgical Access Instruments must be connected to the connectors **156***a*, **156***b* and/or **156***c*, at which point the user may selectively initiate a stimulation signal (preferably, a current signal) from the control unit **122** to a particular Surgical Access Instruments. Stimulating the electrode(s) on these Surgical Access Instruments before, during and/or after establishing operative corridor will cause nerves that come into close or relative proximity to the Surgical Access Instruments to depolarize, producing a response in a myotome associated with the innervated nerve.

The control unit **122** includes a touch screen display **140** and a base **142**, which collectively contain the essential processing capabilities (software and/or hardware) for controlling the monitoring system **120**. The control unit **122** may include an audio unit **118** that emits sounds according to a location of a Surgical Access Instrument with respect to a nerve. The patient module **124** is connected to the control unit **122** via a data cable **144**, which establishes the electrical connections and communications (digital and/or analog) between the control unit **122** and patient module **124**. The main functions of the control unit **122** include receiving user commands via the touch screen display **140**, activating stimulation electrodes on the surgical access instruments, processing signal data according to defined algorithms, displaying received parameters and processed data, and monitoring system status and report fault conditions. The touch screen display **140** is preferably equipped with a graphical user interface (GUI) capable of communicating information to the user and receiving instructions from the user. The display **140** and/or base **142** may contain patient module interface circuitry (hardware and/or software) that commands the stimulation sources, receives digitized signals and other information from the patient module **124**, processes the EMG responses to extract characteristic information for each muscle group, and displays the processed data to the operator via the display **140**.

In one embodiment, the monitoring system **120** is capable of determining nerve direction relative to one or more of the K-wire **42**, dilating cannula **44**, split-retractor **48**, retractor blades **12-18**, and/or the shim elements **22**, **24** before, during and/or following the creation of an operative corridor to a surgical target site. Monitoring system **120** accomplishes this by having the control unit **122** and patient module **124** cooperate to send electrical stimulation signals to one or more of the stimulation electrodes provided on these Surgical Access Instruments. Depending upon the location within a patient (and more particularly, to any neural structures), the stimulation signals may cause nerves adjacent to or in the general proximity of the Surgical Access Instruments to depolarize. This causes muscle groups to innervate and generate EMG responses, which can be sensed via the EMG harness **126**. The nerve direction feature of the system **120** is based on assessing the evoked response of the various muscle myotomes monitored by the system **120** via the EMG harness **126**.

By monitoring the myotomes associated with the nerves (via the EMG harness **126** and recording electrode **127**) and assessing the resulting EMG responses (via the control unit **122**), the surgical access system of the present invention is capable of detecting the presence of (and optionally the distant and/or direction to) such nerves. This provides the ability

to actively negotiate around or past such nerves to safely and reproducibly form the operative corridor to a particular surgical target site, as well as monitor to ensure that no neural structures migrate into contact with the retraction assembly **10** after the operative corridor has been established. In spinal surgery, for example, this is particularly advantageous in that the surgical access system of the present invention may be particularly suited for establishing an operative corridor to an intervertebral target site in a postero-lateral, trans-psoas fashion so as to avoid the bony posterior elements of the spinal column.

FIGS. **18-19** are exemplary screen displays (to be shown on the display **140**) illustrating one embodiment of the nerve direction feature of the monitoring system shown and described with reference to FIGS. **16-17**. These screen displays are intended to communicate a variety of information to the surgeon in an easy-to-interpret fashion. This information may include, but is not necessarily limited to, a display of the function **180** (in this case "DIRECTION"), a graphical representation of a patient **181**, the myotome levels being monitored **182**, the nerve or group associated with a displayed myotome **183**, the name of the instrument being used **184** (e.g. dilating cannula **44**), the size of the instrument being used **185**, the stimulation threshold current **186**, a graphical representation of the instrument being used **187** (in this case, a cross-sectional view of a dilating cannula **44**) to provide a reference point from which to illustrate relative direction of the instrument to the nerve, the stimulation current being applied to the stimulation electrodes **188**, instructions for the user **189** (in this case, "ADVANCE" and/or "HOLD"), and (in FIG. **19**) an arrow **190** indicating the direction from the instrument to a nerve. This information may be communicated in any number of suitable fashions, including but not limited to the use of visual indicia (such as alpha-numeric characters, light-emitting elements, and/or graphics) and audio communications (such as a speaker element). Although shown with specific reference to a dilating cannula (such as at **184**), it is to be readily appreciated that the present invention is deemed to include providing similar information on the display **140** during the use of any or all of the various Surgical Access Instruments of the present invention, including the initial distraction assembly **40** (i.e. the K-wire **42**, dilating cannula **44**, and split dilator **48**), the secondary distraction assembly **50** (FIGS. **13-14**), and/or the retractor blades **12-18** and/or shim elements **22**, **24** of the retraction assembly **10**.

The initial distraction assembly **40** (FIG. **7**) may be provided with one or more electrodes for use in providing the neural monitoring capabilities of the present invention. By way of example only, the K-wire **42** may be equipped with a distal electrode **60**. This may be accomplished by constructing the K-wire **42** for a conductive material, providing outer layer of insulation extending along the entire length with the exception of an exposure that defines the electrode **60**. The electrode **60** has an angled configuration relative to the rest of the K-wire **42** (such as, by way of example only, in the range of between 15 and 75 degrees from the longitudinal axis of the K-wire **42**). The angled nature of the electrode **60** is advantageous in that it aids in piercing tissue as the K-wire **42** is advanced towards the surgical target site.

The angled nature of the distal electrode **60** is also important in that it provides the ability to determine the location of nerves or neural structures relative to the K-wire **42** as it is advanced towards or resting at or near the surgical target site. This "directional" capability is achieved by the fact that the angled nature of the electrode **60** causes the electrical stimulation to be projected away from the distal portion of the K-wire **42** in a focused, or directed fashion. The end result is that nerves or neural structures which are generally closer to the side of the K-wire **42** on which the electrode **60** is disposed will have a higher likelihood of firing or being innervated that nerves or neural structures on the opposite side as the electrode **60**.

The direction to such nerves or neural structures may thus be determined by physically rotating the K-wire **42** at a particular point within the patient's tissue and monitoring to see if any neural stimulation occurs at a given point within the rotation. Such monitoring can be performed via visual observation, a traditional EMG monitoring, as well as the nerve surveillance system disclosed in the above-referenced NeuroVision Applications. If the signals appear more profound or significant at a given point within the rotation, the surgeon will be able tell where the corresponding nerves or neural structures are, by way of example only, by looking at reference information (such as the indicia) on the exposed part of the K-wire **42** (which reference point is preferably set forth in the exact same orientation as the electrode **60**).

The dilating cannula **44** and split dilator **48** may also be provided with electrodes (flat electrodes **64** and angled electrodes **62**, respectively) for the purpose of determining the location of nerves or neural structures relative to the dilating cannula **44** and split-dilator **48** are advanced over the K-wire **44** towards or positioned at or near the surgical target site. Electrodes **62**, **64** may be provided via any number of suitable methods, including but not limited to providing electrically conductive elements within the walls of the dilating cannula **44** and split dilator **48**, such as by manufacturing them from plastic or similar material capable of injection molding or manufacturing them from aluminum (or similar metallic substance) and providing outer insulation layer with exposed regions (such as by anodizing the exterior of the aluminum dilator).

The secondary distraction assembly (including the sequential dilation assembly **50** of FIGS. **13-14**) may be provided with one or more electrodes for use in providing the neural monitoring capabilities of the present invention. By way of example only, it may be advantageous to provide one or more electrodes on the dilating cannulae comprising the sequential dilation assembly **50** for the purpose of conducting neural monitoring before, during and/or after the secondary distraction.

The retractor blades **12-18** and the shim elements **22**, **24** of the present invention may also be provided with one or more electrodes for use in providing the neural monitoring capabilities of the present invention. By way of example only, it may be advantageous to provide one or more electrodes on these components (preferably on the side facing away from the surgical target site) for the purpose of conducting neural monitoring before, during and/or after the retractor blades **12-18** and/or shim elements **22**, **24** have been positioned at or near the surgical target site.

The surgical access system of the present invention may be sold or distributed to end users in any number of suitable kits or packages (sterile and/or non-sterile) containing some or all of the various components described herein. For example, the retraction assembly **10** may be provided such that the mounting assembly **20** is reusable (e.g., autoclavable), while the retractor blades **12-18** and/or shim elements **22**, **24** are disposable. In a further embodiment, an initial kit may include these materials, including a variety of sets of retractor blades **12-18** and/or shim elements **22**, **24** (and extensions **80**) having varying (or "incremental") lengths to account for surgical target sites of varying locations within the patient, optionally color-coded to designate a predetermined length.

As evident from the above discussion and drawings, the present invention accomplishes the goal of providing a novel surgical access system and related methods which involve creating a distraction corridor to a surgical target site, thereafter retracting the distraction corridor to establish and maintain an operative corridor to the surgical target site, and optionally detecting the existence of (and optionally the distance and/or direction to) neural structures before, during and/or after the formation of the distraction and/or operative corridors.

The steps of distraction followed by retraction are advantageous because they provide the ability to more easily position an operative corridor-establishing device through tissue that is strong, thick or otherwise challenging to traverse in order to access a surgical target site. The various distraction systems of the present invention are advantageous in that they provide an improved manner of atraumatically establishing a distraction corridor prior to the use of the retraction systems of the present invention. The various retractor systems of the present invention are advantageous in that they provide an operative corridor having improved cross-sectional area and shape (including customization thereof) relative to the prior art surgical access systems. Moreover, by optionally equipping the various distraction systems and/or retraction systems with one or more electrodes, an operative corridor may be established through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient.

The surgical access system of the present invention can be used in any of a wide variety of surgical or medical applications, above and beyond the spinal applications discussed herein. By way of example only, in spinal applications, any number of implants and/or instruments may be introduced through the working cannula **50**, including but not limited to spinal fusion constructs (such as allograft implants, ceramic implants, cages, mesh, etc.), fixation devices (such as pedicle and/or facet screws and related tension bands or rod systems), and any number of motion-preserving devices (including but not limited to nucleus replacement and/or total disc replacement systems).

While certain embodiments have been described, it will be appreciated by those skilled in the art that variations may be accomplished in view of these teachings without deviating from the spirit or scope of the present application. For example, with regard to the monitoring system **120**, it may be implemented using any combination of computer programming software, firmware or hardware. As a preparatory act to practicing the system **120** or constructing an apparatus according to the application, the computer programming code (whether software or firmware) according to the application will typically be stored in one or more machine readable storage mediums such as fixed (hard) drives, diskettes, optical disks, magnetic tape, semiconductor memories such as ROMs, PROMs, etc., thereby making an article of manufacture in accordance with the application. The article of manufacture containing the computer programming code may be used by either executing the code directly from the storage device, by copying the code from the storage device into another storage device such as a hard disk, RAM, etc. or by transmitting the code on a network for remote execution. As can be envisioned by one of skill in the art, many different combinations of the above may be used and accordingly the present application is not limited by the scope of the appended claims.

What is claimed is:

1. A system for accessing a surgical target site, the system comprising:

a retractor assembly comprising:

a first retractor blade having a first proximal end and a first distal end;

a second retractor blade having a second proximal end and a second distal end;

a third retractor blade having a third proximal end and a third distal end;

a fourth retractor blade having a fourth proximal end and a fourth distal end; and

a blade holder apparatus comprising a mounting structure comprising first, second, third, and fourth support portions, wherein the first support portion is connected to ends of the second and fourth support portions, wherein the second support portion is connected to ends of the first and third support portions, wherein the third support portion is connected to ends of the second and fourth support portions, and wherein the fourth support portion is connected to ends of the third and first support portions such that the first, second, third, and fourth support portions define a mounting structure hole,

wherein each of the first, second, third, and fourth retractor blades are connectable to the mounting structure at the first, second, third, and fourth proximal ends, respectively, such that the first, second, third, and fourth proximal ends are positioned at least partially in the mounting structure hole and the first, second, third, and fourth distal ends extend distally away from the mounting structure so as to define an operative corridor between the first, second, third, and fourth retractor blades that aligns with the mounting structure hole,

wherein at least two of the first, second, third, and fourth retractor blades are hingedly connected to the blade holder apparatus such that at least two of the first, second, third, and fourth distal ends can be independently angled outward with respect to the operative corridor, and

wherein all of the first, second, third, and fourth retractor blades are slidably connected to the blade holder apparatus such that the first, second, third, and fourth distal ends can be independently slid inward and/or outward with respect to the operative corridor; wherein the mounting structure has a substantially square shape, with the first support portion being positioned opposite and substantially parallel to the third support portion and with the second support portion being positioned opposite and substantially parallel to the fourth support portion.

2. The system of claim **1**, wherein the first retractor blades is hingedly connected to the blade holder apparatus so as to pivot about an axis that is parallel to a plane defined by the first, second, third, and fourth support portions.

3. The system of claim **1**, wherein the blade holder apparatus further comprises means for connecting the first, second, third, and fourth retractor blades to the mounting structure.

4. The system of claim **1**, and further comprising:

an initial dilator configured to advance to a targeted spinal disc along a lateral, trans-psoas path to the lumbar spine, an elongate inner member advanceable through an inner lumen of the initial dilator and being configured to penetrate into a lateral aspect of a targeted spinal disc along the lateral, trans-psoas path to the lumbar spine, and a plurality of sequential dilators of sequentially larger diameter deliverable to the targeted spinal disc along the lateral, trans-psoas path to the lumbar spine, wherein at

least one instrument from a group consisting of the initial dilator, the elongate inner member, and the sequential dilators includes a stimulation electrode at a distal tip region to deliver electrical stimulation for nerve monitoring when the stimulation electrode is positioned in the lateral, trans-psoas path, wherein the elongate inner member has a longitudinal length that is greater than a longitudinal length of the initial dilator, and wherein one or more dilators of the plurality of sequential dilators have an outer diameter that is greater than an outer diameter of the initial dilator,

wherein the first, second, third, and fourth retractor blades of are releasably attachable to the blade holder apparatus,

wherein the first, second, third, and fourth retractor blades are configured to maintain the operative corridor along the lateral, trans-psoas path to the lumbar spine after advancement of the plurality of sequential dilators along the lateral, trans-psoas path to the lumbar spine, and

wherein the blade holder apparatus is configured to retain the plurality of retractor blades in a selected position so that the trans-psoas operative corridor is so dimensioned to pass an implant through the trans-psoas operative corridor along the lateral, trans-psoas path to the lumbar spine.

5. The system of claim **4**, and further comprising a monitoring system configured to deliver an electrical stimulation signal to the stimulation electrode of said at least one instrument, configured to monitor electromyographic activity detected by a set of sensor electrodes in muscle myotomes associated with nerves in the vicinity of the spinal disc, and configured to display a numeric stimulation threshold in units of milliAmps indicating an electrical current magnitude required to obtain the electromyographic activity in at least one of said muscle myotomes.

6. The system of claim **1**, wherein the retractor assembly further comprises a fixation element that is releasably attachable to the first refractor blade such that a distal penetration portion of the fixation element extends distally of the first distal end of the first retractor blade and is configured to penetrate into the lumbar spine for affixing the first retractor blade to the lumbar spine.

7. The system of claim **6**, wherein the fixation element is slidably engageable with the first retractor blade and the fixation element includes a proximal portion having a width that is greater than a maximum width of the distal penetration portion of the fixation element.

8. The system of claim **6**, wherein the fixation element configured to be releasably attached to only the first and third retractor blades.

9. The system of claim **1**, and further comprising means for surgeon-driven EMG (electromyography) monitoring for traversing a lateral, trans-psoas path to the lumbar spine.

10. The system of claim **1**, and further comprising:

a nerve surveillance system electrically connectable to at least one of the first, second, third, and fourth retractor blades and configured to stimulate an electrode on at least one of the first, second, third, and fourth retractor blades when inserted into tissue proximate nerves.

11. The system of claim **10**, wherein the nerve surveillance system comprises:

an EMG (electromyography) harness having a plurality of recording electrodes positioned along branches of the EMG harness in pairs, wherein each branch of the EMG harness has a plurality of pairs of recording electrodes; and

a control unit operably connectable to the stimulation electrodes to activate the stimulation electrodes and to the recording electrodes on the EMG harness to receive EMG response signals from the recording electrodes.

12. The system of claim **1**, wherein the first, second, third, and fourth support portions comprise first, second, third, and fourth elongated struts.

13. The system of claim **12**, wherein the first, second, third, and fourth elongated struts are movably connected.

14. The system of claim **12**, wherein the first strut is hingedly connected to the second and fourth elongated struts and where the third strut is hingedly connected to the second and fourth elongated struts.

15. A method of accessing a surgical target site using the system of claim **1**, the method comprising:

forming the operative corridor using a trans-psoas dilator system along a lateral, trans-psoas path to the lumbar spine;

maintaining the operative corridor using the retractor assembly along the lateral, trans-psoas path to the lumbar spine; and

inserting a spinal fusion implant through the operative corridor maintained by the first, second, third, and fourth refractor blades along the lateral, trans-psoas path to the lumbar spine.

16. The method of claim **15**, and further comprising:

performing surgeon-driven EMG (electromyography) monitoring while traversing the lateral, trans-psoas path to the lumbar spine.

17. The method of claim **15**, wherein the first retractor blade is a posterior-most retractor blade, the second retractor blade is an anterior-most retractor blade, the third retractor blade is a caudal-most retractor blade, and the fourth retractor blade is a cephalad-most retractor blade.

18. The method of claim **17**, wherein at least the posterior-most retractor blade and the anterior-most retractor blade are hingedly connected to the blade holder apparatus.

19. The method of claim **18**, and further comprising:

advancing a fixation element into the working corridor so as to be attached to the posterior-most retractor blade and advanced into the disc space so as to distract adjacent vertebral bodies.

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